A study of Non-Steroidal Or Opioid Analgesia Use for Children with Musculoskeletal Injuries: The No OUCH Trials

REB # :	Screening ID	Enrolment Date
PI: Dr. Samina Ali	____ ____ ____ - ____ ____ ____ ____ (site) (screening number)	__ __ / __ __ __ / 2 0 __ __ dd mmm yyyy

REDCap Forms: Summary

Time Point / Section	
Screening	➢ Pre-Screening ➢ Eligibility ➢ Informed Consent ➢ Evaluation 1 (TR) ➢ Injury Details and Previous History ➢ Medical Oversight of Screening
T0 (Time of Study Drug Administration)	➢ Selection of Family Preference ➢ Study Drug Administration ➢ Evaluation 2 (T0) ➢ Evaluation Time point Calculator (will be programmed in REDCap) ➢ Contact Information Sheet ➢ In PED Caregiver Survey
T30	➢ Evaluation 3
T60	➢ Evaluation 4
T90	➢ Evaluation 5
T120	➢ Evaluation 6
TME (Time of Medical Exam)	➢ Evaluation 7
TXR (Time of X-Ray)	➢ Evaluation 8
PRE-Discharge	➢ ED Discharge Evaluation (only complete if discharged before 120 min) ➢ Pre-discharge Questions (complete with ALL families)
POST-Discharge	➢ Post-discharge Questions
Follow-up Survey 1 (24h)	➢ Call Log ➢ Follow-up Survey 1 (24h)
Follow-up Survey 2 (1-2w)	➢ Call Log ➢ Follow-up Survey 1 (1-2w)
Logs	➢ Concomitant and Rescue Medications ➢ Adverse Events ➢ Protocol Deviations ➢ Unanticipated Problems ➢ Early Withdrawal Form

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Pre-Screening (electronic SEMO Log)

Site	☐ Edmonton AB (1) ☐ Calgary AB (2) ☐ Winnipeg MB (3) ☐ Montreal QC (4) ☐ London ON (5) ☐ Ottawa ON (6)	
Name of Research Nurse completing screening / enrolment	First and Last Name	
Date and Time of Triage	_____/_____/_____ dd mmm yyyy _____:_____ (24 hour clock)	
Age	_____ years	
Sex	☐ Male	☐ Female
Was the family approached for this study?	☐ Yes	☐ No
If NO, specify reason and STOP HERE.	☐ Family refused overall consent to be approached for research ☐ Legal guardian not present ☐ RA busy with another study ☐ Did not meet eligibility criteria, specify _____ ☐ Other, Specify _____	
If YES, continue to Eligibility.		

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Eligibility

Was verbal consent for screening obtained from the family? ☐ Yes ☐ No

Inclusion Criteria

1. Child aged 6-17 years	☐ Yes	☐ No
2. Presenting to the emergency department with an acute limb injury (<24 hours old) that is neither obviously deformed nor having neuro-vascular compromise (as assessed by the triage nurse)	☐ Yes	☐ No
3. Self-reported pain score ≥ 5 on the 0 to 10 verbal Numerical Rating Scale (vNRS) at triage	☐ Yes	☐ No

Exclusion Criteria

1. Deemed to require intravenous (IV) or intranasal (IN) pain medications by the clinical team	☐ Yes	☐ No
2. Previously known hypersensitivity to study medications	☐ Yes	☐ No
3. Acetaminophen or non-steroidal anti-inflammatory medication (NSAID) use, within 3 hours prior to recruitment	☐ Yes	☐ No
4. Opioid use within 1 hour prior to recruitment	☐ Yes	☐ No
5. Caregiver and/or child cognitive impairment precluding the ability to self-report pain or respond to study questions	☐ Yes	☐ No
6. Injury suspected to be due to non-accidental trauma/ child abuse (as assessed by the triage nurse or reported by the family)	☐ Yes	☐ No
7. Suspected multi-limb fracture	☐ Yes	☐ No
8. Chronic pain that necessitates daily analgesic use	☐ Yes	☐ No
9. Hepatic or renal disease/dysfunction	☐ Yes	☐ No
10. Bleeding disorder	☐ Yes	☐ No
11. Known pregnancy	☐ Yes	☐ No
12. Vomiting that precludes the ability to take oral medications (as determined by the family)	☐ Yes	☐ No
13. Caregiver and/or child inability to communicate fluently in English or French in the absence of a native language interpreter	☐ Yes	☐ No
14. Caregiver unavailable for follow-up	☐ Yes	☐ No
15. Previous enrollment in study	☐ Yes	☐ No

REDCap to display if family is eligible or not based on above answers. RRN to confirm below.

Is family eligible for study?	☐ Yes	☐ No

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PI: Dr. Samina Ali	___ ___ ___ - ___ ___ ___ ___ (site) (screening number)	__ __ / __ __ __ / 2 0 __ __ dd mmm yyyy

Informed Consent

Has written informed consent been obtained?	☐ Yes ☐ No
If NO, specify reason and STOP HERE.	☐ Declined consent ☐ Declined assent ☐ Other, please specify _____
If YES, specify the date and time of Informed Consent:	_____/_____/_____ dd mmm yyyy _____:_____ (24 hour clock)
Has a copy of the signed informed consent been given to the family?	☐ Yes ☐ No
If no, specify reason:	
Has written assent been obtained?	☐ Yes ☐ No ☐ No, but verbal assent was obtained and documented
If no, specify reason and STOP HERE.	
Has a copy of the signed assent been given to the family?	☐ Yes ☐ No
If no, specify reason:	
Permission to contact for future studies?	☐ Yes ☐ No
[Stollery Site ONLY] Would you be interested in being contacted, later, about a second related study? We want to better understand how parents make medical decisions for their children when they are injured and have pain.	☐ Yes ☐ No

If ALL the inclusion and exclusion criteria are met AND written consent and assent have been obtained, please proceed.

If NOT, please STOP here.

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REB # :	Screening ID	Enrolment Date
PI: Dr. Samina Ali	___ ___ ___ - ___ ___ ___ ___ (site) (screening number)	__ __ / __ __ __ / 2 0 __ __ dd mmm yyyy

Evaluation # 1 (TR – Recruitment)

Was this evaluation completed?	☐ Yes ☐ No
If Yes, continue. If No, specify reason:	
Date and Time of evaluation # 1:	_____/_____/_____ dd mmm yyyy _____:_____ (24 hour clock)
Vital Signs: *Record triage vital signs here.* ***Please measure a new set of vital signs if triage time is ≥60 minutes from time of recruitment.***	HR: _____ bpm RR: _____ rpm Sat: _____ % BP: _____ / _____ mmHg
Pain Scores: **vNRS** *"On a scale of 0 to 10, where 0 is no pain and 10 is the worst pain you can imagine, what is your pain level now?"* **VAS** *"What is your pain level on this sliding scale, where 0 means absence of pain and 100 is the worst pain you have ever experienced?"* **FPS-R** *"These faces show how much something can hurt. This face (point to left most face) shows no pain. The faces show more and more pain (point from left to right) up to this one (point to right most face) – it shows very much pain. Can you point to the face that shows how much you hurt right now?"* *Note: say "hurt" or "pain" whichever seems right for a particular child*	_____/10 _____/100 mm ☐ 0 ☐ 2 ☐ 4 ☐ 6 ☐ 8 ☐ 10

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REB # :	Screening ID	Enrolment Date
PI: Dr. Samina Ali	___ ___ ___ - ___ ___ ___ ___ (site) (screening number)	__ __ / __ __ __ / 2 0 __ __ dd mmm yyyy

Injury Details and Previous History

Date and Time of Injury:	_____/_____/_____ _____:_____ dd mmm yyyy (24 hour clock)

Location of Primary Injury: Please select the location of the PRIMARY injury (pick ONE only)	
☐ Single or Multiple Fingers (if ONLY injury) ☐ Hand ☐ Wrist ☐ Forearm ☐ Elbow ☐ Upper Arm ☐ Shoulder ☐ Collarbone	☐ Single or Multiple Toes (if ONLY injury) ☐ Foot ☐ Ankle ☐ Lower leg ☐ Knee ☐ Thigh ☐ Hip

Concomitant Digit Injury:	
Is there a concomitant digit injury present **on the same limb**?	☐ Yes ☐ No
If yes, please select the location of the secondary injury (pick ONE only)	☐ Single or Multiple fingers ☐ Single or Multiple toes

Concomitant Medications Have any medications been given since the injury?	☐ Yes – (Fill out Concomitant Medication Form) ☐ No

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PI: Dr. Samina Ali	___ ___ ___ - ___ ___ ___ ___ (site) (screening number)	__ __ / __ __ __ / 2 0 __ __ dd mmm yyyy

Medical Oversight of Screening

Eligibility of the participant has been confirmed by:	☐ PI / Site Investigator (in person) ☐ PI / Site Investigator (by phone) ☐ Third party physician Purpose: to review the inclusion and exclusion criteria on this form and confirm that the patient meets the criteria listed.
If PI/ Site Investigator, specify: PI / Site Investigator Physician Name: Date and time of confirmation:	_____ _____/_____/_____ _____:_____ dd mmm yyyy (24 hour clock)
If Third party physician, specify: Third party Physician Name: Date and time of confirmation:	_____ _____/_____/_____ _____:_____ dd mmm yyyy (24 hour clock)

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PI: Dr. Samina Ali	____ ____ ____ - ____ ____ ____ ____ (site) (screening number)	__ __ / __ __ __ / 2 0 __ __ dd mmm yyyy

Selection of Family Preference

To Caregiver and Child: *"At this point, we need you to tell us which study group you would like to participate in: Group 1 or Group 2. Regardless of which study you choose, you / your child will, at minimum, receive ibuprofen (Advil) for their pain. Both groups include commonly used pain medicines for this type of pain, however Group 2 includes all three of the pain medicine options offered in this study. So, if you don't have a preference, we will assign you to Group 2.*

- *If you choose Group 2, you/your child will have an equal chance of receiving either:*
  - *Ibuprofen (Advil) AND placebos (inactive ingredient)*
  - *Ibuprofen (Advil) AND acetaminophen (Tylenol)*
  - *Ibuprofen (Advil) AND hydromorphone (Dilaudid)*

- *If you choose Group 1, you/your child will have an equal chance of receiving either:*
  - *Ibuprofen (Advil) AND placebo (inactive ingredient)*
  - *Ibuprofen (Advil) AND acetaminophen (Tylenol)*

To help you in making your choice, here is some more information about these medicines.

1. *Ibuprofen (Advil) is typically provided for the kind of injury you/your child has, but it may not always be strong enough to treat a child's pain.*
2. *When a child needs something stronger than ibuprofen (Advil) for their pain, acetaminophen (Tylenol) and opioid medicines like hydromorphone (Dilaudid) are the most commonly recommended pain killers to be added to the ibuprofen.*
3. *Please remember that if you feel that you/your child needs more pain medicine at any point during the study period, you or our research nurse can let your doctor know right away.*

- *Which study would you like to be a part of: Group 1 or Group 2?*

- [NOTE: If the family wishes to speak to a health care professional prior to making their study choice, the RA will then identify a clinical team member to aid them.]

Indicate family preference below:

☐ **Group 1:** Non-Opioid trial [N]
☐ **Group 2:** Opioid trial [O]
☐ No preference → Proceed to enroll in ☐ **Group 2:** Opioid trial [O]
☐ Family unable to reach consensus regarding preference. [If this is chosen, STOP enrolment now]

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Once the **Preference Group** has been selected by the family, please retrieve the following study medication kit from your medication dispensing area:

Pharmacy Kit Number:

____ ____ ____ - ____ - ____ ____ ____

(site - preference group - patient number)

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REB # :	Study ID	Enrolment Date
PI: Dr. Samina Ali	____ ____ ____ - ____ - ____ ____ ____ (site - preference group - patient number)	__ __ / __ __ __ / 2 0 __ __ dd mmm yyyy

Study Drugs Administration

Confirmed that the pharmacy kit is not expired?	☐ Yes ☐ No* *If "**NO**", check before proceeding*
Are the noted min. and max. temperatures of the drug storage fridge within the required ranges, today?	☐ Yes ☐ No* *If "**NO**", check temperatures before proceeding*
Weight:	_____kg ☐ Measured on scale ☐ Estimate provided by parent
Ibuprofen (40mg/ml) (up to **600 mg** maximum – **15 ml** maximum)	**Dose: 10 mg per kg** Calculation: _____kg x 10 = _____mg **Volume: 40mg = 1 ml** Calculation: _____mg ÷ 40mg/ml = _____ml **Volume actually dispensed to patient: _____ml**
Acetaminophen or Placebo (80mg/ml) (up to **1000 mg** maximum – **12.5 ml** maximum)	**Dose: 15 mg per kg** Calculation: _____kg x 15 = _____mg **Volume: 80mg = 1 ml** Calculation: _____mg ÷ 80 mg/kg = _____ml **Volume actually dispensed to patient: _____ml**

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Hydromorphone or Placebo (1mg/ml) (up to **5 mg** maximum – **5 ml** maximum) ONLY for participants enrolled in Group 2: Opioid trial	**Dose: 0.05 mg per kg** Calculation: _____kg x 0.05 = _____mg **Volume: 1 mg = 1 ml** Calculation: _____mg ÷ 1 mg/ml = _____ml **Volume actually dispensed to patient: _____ml**
*Dose calculation and dispensing in syringe must be verified by a second nurse:	Verified by: _____
Date and time of study drugs administration:	_____/_____/_____ dd mmm yyyy _____:_____ (24 hour clock)
Has the participant taken the full dose of each syringe?	☐ Yes ☐ No* *If "**NO**", please comment*
Were all study drugs administered one after the other?	☐ Yes ☐ No* *If "**NO**", please comment*
Was dispensing of the study drugs recorded on the patient's clinical chart?	☐ Yes ☐ No* *If "**NO**", please comment*
Comments:	

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PI: Dr. Samina Ali	____ ____ ____ - ____ - ____ ____ ____ (site - preference group - patient number)	__ __ / __ __ __ / 2 0 __ __ dd mmm yyyy

Evaluation # 2 (T0 – Immediately after Study Drug Administration)

Time due: dd/ mmm/ yyyy HH:MM ± 10 min

Was this evaluation completed?	☐ Yes ☐ No
If Yes, continue. If No, specify reason:	
Date and Time of evaluation # 2:	_____/_____/_____ dd mmm yyyy _____:_____ (24 hour clock)
Pain and Sedation Scores: **vNRS** *"On a scale of 0 to 10, where 0 is no pain and 10 is the worst pain you can imagine, what is your pain level now?"* **VAS** *"What is your pain level on this sliding scale, where 0 means absence of pain and 100 is the worst pain you have ever experienced?"* **FPS-R** *"These faces show how much something can hurt. This face (point to left most face) shows no pain. The faces show more and more pain (point from left to right) up to this one (point to right most face) – it shows very much pain. Can you point to the face that shows how much you hurt right now?" Note: say "hurt" or "pain" whichever seems right for a particular child* **RSS**	_____/10 _____/100 mm ☐ 0 ☐ 2 ☐ 4 ☐ 6 ☐ 8 ☐ 10 _____/6

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REB # :	Study ID	Enrolment Date
PI: Dr. Samina Ali	____ ____ ____ - ____ - ____ ____ ____ (site - preference group - patient number)	__ __ / __ __ __ / 2 0 __ __ dd mmm yyyy

Contact Information Sheet

Child's Name:	_____ _____ First name Last name
Age:	_____ years
Sex:	☐Male ☐Female
Caregiver's Name:	_____ _____ First name Last name Specify relationship to child: _____
Preferred Mode of Contact:	☐Email ☐Phone
Email:	
Preferred Phone Number:	(_____) _____ - _____
Alternate Phone Number:	(_____) _____ - _____
Time for follow up call:	☐ AM ☐ PM Specify: _____

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REB # :	Study ID	Enrolment Date
PI: Dr. Samina Ali	____ ____ ____ - ____ - ____ ____ ____ **(site - preference group - patient number)**	__ __ / __ __ __ / 2 0 __ __ dd mmm yyyy

In PED Caregiver Survey

Your Information	
What is YOUR age, in years?	_____ years
What is YOUR sex?	☐ Male ☐ Female ☐ Other, specify: _____ ☐ Decline to answer
What is your home postal code? (1st 3 digits only)	__ __ __
What is your highest level of Education?	☐ Elementary School ☐ High School or some High School ☐ Diploma/Certificate ☐ Some Post-Secondary/University ☐ University/Professional Degree ☐ Decline to answer
What is your annual household income from all sources?	☐ Less than or equal to $25,000 ☐ $25,001 to $50,000 ☐ $50,001 to $75,000 ☐ $75,000 to $100,000 ☐ Greater than $100,000 ☐ Decline to answer

Injury Details	
How did your child's injury occur?	☐ Motor Vehicle Collision/ Road Traffic Accident ☐ Sports Injury ☐ Ice Hockey/ Hockey ☐ Football ☐ Soccer ☐ Wrestling ☐ Basketball ☐ Gymnastics/ Cheerleading ☐ Skiing/ Snowboarding ☐ Biking ☐ Other sport, specify: _____ ☐ Trampoline

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	☐ Other play or activity ☐ Other Slip, Trip or Fall ☐ Other mechanism, specify: _____
Was the sports, play or activity supervised (ie. Were you or another adult there watching your child)?	☐ Yes ☐ No ☐ Unsure
Where did your child's injury occur?	☐ Sports Field/ Arena ☐ In School/ School playground ☐ Playground/ Park ☐ Home/ Friend's home ☐ Road ☐ Other, please specify: _____

Study Preference	
If they chose the Non-Opioid trial (Group 1): Please tell us your reason(s) for choosing **Group 1**, ie. the study with the possibility of receiving one of the following: o Ibuprofen only (Advil) o Ibuprofen (Advil) and Acetaminophen (Tylenol) *Choose all that apply*	☐ I do not believe my child's pain is/ will be severe enough to require an opioid medicine (Hydromorphone/ Dilaudid) ☐ I did not want my child to receive an opioid medicine ☐ I do not think my child is old enough to receive an opioid medicine ☐ I trust that both medicines in this study would work for my child, with their current level of pain ☐ I think my child will get better care if they are a part of this study (ex. they will get treated faster, get close care from the research nurse etc.) ☐ Other, please specify: _____
If they chose the Opioid trial (Group 2): Please tell us your reason(s) for choosing **Group 2**, ie. the study with the possibility of receiving one of the following: o Ibuprofen only (Advil) o Ibuprofen (Advil) and Acetaminophen (Tylenol) o Ibuprofen (Advil) and Hydromorphone (Dilaudid)	☐ I wanted to have the option of all 3 medicines, or combination of medicines, available to us ☐ I wanted/hoped that my child will receive the opioid medicine (Hydromorphone/ Dilaudid) specifically ☐ I believe that my child's pain is/ will be severe enough to require an opioid medicine ☐ I believe that the pain relief benefits of the opioid medicine are greater than any possible side effects ☐ I trust that any of the 3 options in this study would work for my child, with their current level of pain

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REB # :	Study ID	Enrolment Date
PI: Dr. Samina Ali	____ ____ ____ - ____ - ____ ____ ____ (site - preference group - patient number)	__ __ / __ __ __ / 2 0 __ __ dd mmm yyyy

Choose all that apply	☐ I think my child will get better care if they are a part of this study (ex. they will get treated faster, get close care from the research nurse etc.) ☐ Participating in this study will help researchers learn more about the use of opioids for treating injury-related pain for children in the future ☐ Other, please specify: _____

Experience with Opioid Pain Medicines	
Have YOU ever been prescribed or given an opioid medicine by a health care provider, in a clinic or hospital? *Ex. Hydromorphone (Dilaudid), Morphine, Oxycodone (OxyContin, Percocet), Codeine, Fentanyl, Hydrocodone (Vicodin)*	☐ Yes ☐ No ☐ Unsure
Have any of your FAMILY MEMBERS ever been prescribed or given an opioid medicine by a health care provider, in a clinic or hospital? *Ex. Hydromorphone (Dilaudid), Morphine, Oxycodone (OxyContin, Percocet), Codeine, Fentanyl, Hydrocodone (Vicodin)*	☐ Yes ☐ No ☐ Unsure
If yes, was this family member a CHILD?	☐ Yes ☐ No ☐ Decline to Answer
Have you or a family member ever been diagnosed with a substance use disorder, or addiction to drugs/ alcohol?	☐ Yes ☐ No ☐ Unsure ☐ Decline to answer
If yes, can you please specify which drug(s)/ substances?	[Free text]

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REB # :	Study ID	Enrolment Date
PI: Dr. Samina Ali	____ ____ ____ - ____ - ____ ____ ____ (site - preference group - patient number)	__ __ / __ __ __ / 2 0 __ __ dd mmm yyyy

Evaluation # 3 (T30 – 30 minutes after study drugs administration)

Time due: dd/ mmm/ yyyy HH:MM ± 15 min

Was this evaluation completed?	☐ Yes ☐ No
If Yes, continue. If No, specify reason:	☐ Patient discharged before specified evaluation time ☐ Other: _____
Date and Time of evaluation # 3:	_____/_____/_____ dd mmm yyyy _____:_____ (24 hour clock)
Vital Signs:	HR: _____ bpm RR: _____ rpm Sat: _____ % BP: _____ / _____ mmHg
Pain and Sedation Scores: **vNRS** *"On a scale of 0 to 10, where 0 is no pain and 10 is the worst pain you can imagine, what is your pain level now?"* **VAS** *"What is your pain level on this sliding scale, where 0 means absence of pain and 100 is the worst pain you have ever experienced?"* **FPS-R** *"These faces show how much something can hurt. This face (point to left most face) shows no pain. The faces show more and more pain (point from left to right) up to this one (point to right most face) – it shows very much pain. Can you point to the face that shows how much you hurt right now?"* *Note: say "hurt" or "pain" whichever seems right for a particular child* **RSS**	_____/10 _____/100 mm ☐ 0 ☐ 2 ☐ 4 ☐ 6 ☐ 8 ☐ 10 _____/6
Any adverse events or side effects? *If "**YES**", complete a separate entry for each AE on the AE Form. Do not suggest any AEs to the participant; let him/ her answer spontaneously.*	☐ Yes – (Fill out Adverse Events Form) ☐ No

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REB # :	Study ID	Enrolment Date
PI: Dr. Samina Ali	____ ____ ____ - ____ - ____ ____ ____ (site - preference group - patient number)	__ __ / __ __ __ / 2 0 __ __ dd mmm yyyy

Evaluation # 4 (T60 – 60 minutes after study drugs administration)

Time due: dd/ mmm/ yyyy HH:MM ± 15 min

Was this evaluation completed?	☐ Yes ☐ No
If Yes, continue. If No, specify reason:	☐ Patient discharged before specified evaluation time ☐ Other: _____
Date and Time of evaluation # 4:	_____/_____/_____ dd mmm yyyy _____:_____ (24 hour clock)
Vital Signs:	HR: _____ bpm RR: _____ rpm Sat: _____ % BP: _____ / _____ mmHg
Pain and Sedation Scores: **vNRS** *"On a scale of 0 to 10, where 0 is no pain and 10 is the worst pain you can imagine, what is your pain level now?"* **VAS** *"What is your pain level on this sliding scale, where 0 means absence of pain and 100 is the worst pain you have ever experienced?"* **FPS-R** *"These faces show how much something can hurt. This face (point to left most face) shows no pain. The faces show more and more pain (point from left to right) up to this one (point to right most face) – it shows very much pain. Can you point to the face that shows how much you hurt right now?"* *Note: say "hurt" or "pain" whichever seems right for a particular child* **RSS**	_____/10 _____/100 mm ☐ 0 ☐ 2 ☐ 4 ☐ 6 ☐ 8 ☐ 10 _____/6
Any adverse events or side effects? *If "**YES**", complete a separate entry for each AE on the AE Form. Do not suggest any AEs to the participant; let him/ her answer spontaneously.*	☐ Yes – (Fill out Adverse Events Form) ☐ No

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REB # :	Study ID	Enrolment Date
PI: Dr. Samina Ali	____ ____ ____ - ____ - ____ ____ ____ (site - preference group - patient number)	__ __ / __ __ __ / 2 0 __ __ dd mmm yyyy

Evaluation # 5 (T90 – 90 minutes after study drugs administration)

Time due: dd/ mmm/ yyyy HH:MM ± 15 min

Was this evaluation completed?	☐ Yes ☐ No
If Yes, continue. If No, specify reason:	☐ Patient discharged before specified evaluation time ☐ Other: _____
Date and Time of evaluation # 5:	_____/_____/_____ dd mmm yyyy _____:_____ (24 hour clock)
Vital Signs:	HR: _____ bpm RR: _____ rpm Sat: _____ % BP: _____ / _____ mmHg
Pain and Sedation Scores: **vNRS** *"On a scale of 0 to 10, where 0 is no pain and 10 is the worst pain you can imagine, what is your pain level now?"* **VAS** *"What is your pain level on this sliding scale, where 0 means absence of pain and 100 is the worst pain you have ever experienced?"* **FPS-R** *"These faces show how much something can hurt. This face (point to left most face) shows no pain. The faces show more and more pain (point from left to right) up to this one (point to right most face) – it shows very much pain. Can you point to the face that shows how much you hurt right now?" Note: say "hurt" or "pain" whichever seems right for a particular child* **RSS**	_____/10 _____/100 mm ☐ 0 ☐ 2 ☐ 4 ☐ 6 ☐ 8 ☐ 10 _____/6
Any adverse events or side effects? *If "**YES**", complete a separate entry for each AE on the AE Form. Do not suggest any AEs to the participant; let him/ her answer spontaneously.*	☐ Yes – (Fill out Adverse Events Form) ☐ No

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REB # :	Study ID	Enrolment Date
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Evaluation # 6 (T120 – 120 minutes after study drugs administration)

Time due: dd/ mmm/ yyyy HH:MM ± 15 min

Was this evaluation completed?	☐ Yes ☐ No
If Yes, continue. If No, specify reason:	☐ Patient discharged before specified evaluation time ☐ Other: _____
Date and Time of evaluation # 6:	_____/_____/_____ dd mmm yyyy _____:_____ (24 hour clock)
Vital Signs:	HR: _____ bpm RR: _____ rpm Sat: _____ % BP: _____ / _____ mmHg
Pain and Sedation Scores: **vNRS** *"On a scale of 0 to 10, where 0 is no pain and 10 is the worst pain you can imagine, what is your pain level now?"* **VAS** *"What is your pain level on this sliding scale, where 0 means absence of pain and 100 is the worst pain you have ever experienced?"* **FPS-R** *"These faces show how much something can hurt. This face (point to left most face) shows no pain. The faces show more and more pain (point from left to right) up to this one (point to right most face) – it shows very much pain. Can you point to the face that shows how much you hurt right now?" Note: say "hurt" or "pain" whichever seems right for a particular child* **RSS**	_____/10 _____/100 mm ☐ 0 ☐ 2 ☐ 4 ☐ 6 ☐ 8 ☐ 10 _____/6
Any adverse events or side effects? *If "**YES**", complete a separate entry for each AE on the AE Form. Do not suggest any AEs to the participant; let him/ her answer spontaneously.*	☐ Yes – (Fill out Adverse Events Form) ☐ No

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REB # :	Study ID	Enrolment Date
PI: Dr. Samina Ali	____ ____ ____ - ____ - ____ ____ ____ (site - preference group - patient number)	__ __ / __ __ __ / 2 0 __ __ dd mmm yyyy

Evaluation # 7 (TME, Time of Medical Examination)

Was this evaluation completed?	☐ Yes ☐ No
If Yes, continue. If No, specify reason:	
Date and Time of medical exam:	_____/_____/_____ dd mmm yyyy _____:_____ (24 hour clock)
Vital Signs:	HR: _____ bpm RR: _____ rpm Sat: _____ % BP: _____ / _____ mmHg
Pain and Sedation Scores: **vNRS** *"On a scale of 0 to 10, where 0 is no pain and 10 is the worst pain you can imagine, what is your pain level now?"* **VAS** *"What is your pain level on this sliding scale, where 0 means absence of pain and 100 is the worst pain you have ever experienced?"* **FPS-R** *"These faces show how much something can hurt. This face (point to left most face) shows no pain. The faces show more and more pain (point from left to right) up to this one (point to right most face) – it shows very much pain. Can you point to the face that shows how much you hurt right now?"* *Note: say "hurt" or "pain" whichever seems right for a particular child* **RSS**	_____/10 _____/100 mm ☐ 0 ☐ 2 ☐ 4 ☐ 6 ☐ 8 ☐ 10 _____/6
Any adverse events or side effects? *If "**YES**", complete a separate entry for each AE on the AE Form. Do not suggest any AEs to the participant; let him/ her answer spontaneously.*	☐ Yes – (Fill out Adverse Events Form) ☐ No

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REB # :	Study ID	Enrolment Date
PI: Dr. Samina Ali	____ ____ ____ - ____ - ____ ____ ____ (site - preference group - patient number)	__ __ / __ __ __ / 2 0 __ __ dd mmm yyyy

Evaluation # 8 (TXR – Time following X-Ray procedure +/- 30 minutes)

Did the patient have an X-ray?	☐ Yes ☐ No
If Yes, Was the post- X-ray evaluation completed?	☐ Yes ☐ No
If Yes, continue. If No, specify reason:	
Date and Time of X-ray:	_____/_____/_____ dd mmm yyyy _____:_____ (24 hour clock)
Date and Time of evaluation # 8:	_____/_____/_____ dd mmm yyyy _____:_____ (24 hour clock)
Vital Signs:	HR: _____ bpm RR: _____ rpm Sat: _____ % BP: _____ / _____ mmHg
Pain and Sedation Scores: **vNRS** *"On a scale of 0 to 10, where 0 is no pain and 10 is the worst pain you can imagine, what is your pain level now?"* **VAS** *"What is your pain level on this sliding scale, where 0 means absence of pain and 100 is the worst pain you have ever experienced?"* **FPS-R** *"These faces show how much something can hurt. This face (point to left most face) shows no pain. The faces show more and more pain (point from left to right) up to this one (point to right most face) – it shows very much pain. Can you point to the face that shows how much you hurt right now?" Note: say "hurt" or "pain" whichever seems right for a particular child* **RSS**	_____/10 _____/100 mm ☐ 0 ☐ 2 ☐ 4 ☐ 6 ☐ 8 ☐ 10 _____/6

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REB # :	Study ID	Enrolment Date
PI: Dr. Samina Ali	**____ ____ ____ - ____ - ____ ____ ____** **(site - preference group - patient number)**	__ __ / __ __ __ / 2 0 __ __ dd mmm yyyy

Any adverse events or side effects? *If "**YES**", complete a separate entry for each AE on the AE Form. Do not suggest any AEs to the participant; let him/ her answer spontaneously.*	☐ Yes – (Fill out Adverse Events Form) ☐ No

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REB # :	Study ID	Enrolment Date
PI: Dr. Samina Ali	____ ____ ____ - ____ - ____ ____ ____ (site - preference group - patient number)	__ __ / __ __ __ / 2 0 __ __ dd mmm yyyy

ED Discharge Evaluation

ED Discharge Evaluation *(To be done only if discharged before 120 minutes)*	
Was the patient discharged before 120 minutes?	☐ Yes ☐ No
If Yes, Was this evaluation completed?	☐ Yes ☐ No
If Yes, continue. If No, specify reason:	
Date and Time of ED Discharge:	_____/_____/_____ dd mmm yyyy _____:_____ (24 hour clock)
Vital Signs:	HR: _____ bpm RR: _____ rpm Sat: _____ % BP: _____ / _____ mmHg
Pain and Sedation Scores: **vNRS** *"On a scale of 0 to 10, where 0 is no pain and 10 is the worst pain you can imagine, what is your pain level now?"* **VAS** *"What is your pain level on this sliding scale, where 0 means absence of pain and 100 is the worst pain you have ever experienced?"* **FPS-R** *"These faces show how much something can hurt. This face (point to left most face) shows no pain. The faces show more and more pain (point from left to right) up to this one (point to right most face) – it shows very much pain. Can you point to the face that shows how much you hurt right now?"* *Note: say "hurt" or "pain" whichever seems right for a particular child* **RSS**	_____/10 _____/100 mm ☐ 0 ☐ 2 ☐ 4 ☐ 6 ☐ 8 ☐ 10 _____/6
Any adverse events or side effects? *If "**YES**", complete a separate entry for each AE on the AE Form. Do not suggest any AEs to the participant; let him/ her answer spontaneously.*	☐ Yes – (Fill out Adverse Events Form) ☐ No

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REB # :	Study ID	Enrolment Date
PI: Dr. Samina Ali	**____ ____ ____ - ____ - ____ ____ ____** **(site - preference group - patient number)**	__ __ / __ __ __ / 2 0 __ __ dd mmm yyyy

Reason for early termination?	☐ Procedural sedation used for a reduction* ☐ Left ED prior to evaluation ☐ Left without being seen ☐ Other, please specify _____ * Fill out Concomitant Medication Form

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REB # :	Study ID	Enrolment Date
PI: Dr. Samina Ali	____ ____ ____ - ____ - ____ ____ ____ (site - preference group - patient number)	__ __ / __ __ __ / 2 0 __ __ dd mmm yyyy

PRE-Discharge Questions

Question for Research Nurse	
Which drug, or combination of drugs, do you think the child received for this study?	☐ Ibuprofen alone or ☐ Ibuprofen + Acetaminophen or ☐ Ibuprofen + Hydromorphone

Questions for Parent/ Caregiver	
Which drug, or combination of drugs, do you (parent/ caregiver) think your child received for this study?	☐ Ibuprofen alone or ☐ Ibuprofen + Acetaminophen or ☐ Ibuprofen + Hydromorphone
How do you feel about the pain treatment provided by the study medicine today?	☐ Very Satisfied ☐ Somewhat Satisfied ☐ Neutral ☐ Somewhat dissatisfied ☐ Very dissatisfied
Do you feel that that the medicines that your child received provided adequate/ enough pain relief for your child?	☐ Yes ☐ No ☐ Unsure
Would you accept the same medicine for your child, in the unlikely event of a similar injury in the future?	☐ Yes ☐ No ☐ Unsure
Why? Why Not?	Free Text

Questions for Child	
How happy were you with the pain treatment from the study medicine today?	☐ Very happy ☐ Somewhat happy ☐ Neutral ☐ Somewhat sad ☐ Very sad
Would you take the same medicine if you had the same injury again?	☐ Yes ☐ No

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REB # :	Study ID	Enrolment Date
PI: Dr. Samina Ali	____ ____ ____ - ____ - ____ ____ ____ (site - preference group - patient number)	__ __ / __ __ __ / 2 0 __ __ dd mmm yyyy

	☐ Unsure
Why? Why Not?	Free Text

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REB # :	Study ID	Enrolment Date
PI: Dr. Samina Ali	____ ____ ____ - ____ - ____ ____ ____ (site - preference group - patient number)	__ __ / __ __ __ / 2 0 __ __ dd mmm yyyy

POST-Discharge Questions

Questions for Treating ED Physician	
Which drug(s) would you have chosen to give this child?	☐ Ibuprofen alone or ☐ Ibuprofen + Acetaminophen or ☐ Ibuprofen + Hydromorphone ☐ other, please specify
Which drug(s) do you think that the child received?	☐ Ibuprofen alone or ☐ Ibuprofen + Acetaminophen or ☐ Ibuprofen + Hydromorphone

Unblinding	
Was the study unblinded during the ED visit?	☐ Yes, please explain. ☐ No

Co-Interventions

Were any interventions done during the ED visit? ☐ Yes* ☐ No

** If "**YES**", please fill out the table below*

Intervention	Administered?	Date and Time of Administration (dd/ mmm/ yyyy HH:MM)	Comments
Reduction of the fracture?	☐ Yes ☐ No		
Splint?	☐ Yes ☐ No		
Cast?	☐ Yes ☐ No		
Ice?	☐ Yes ☐ No		
Distraction?	☐ Yes ☐ No		
Other? Please specify: _____	☐ Yes ☐ No		

If a procedural sedation or a medication has been administered, please fill out the Concomitant Medication Form.

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REB # :	Study ID	Enrolment Date
PI: Dr. Samina Ali	____ ____ ____ - ____ - ____ ____ ____ **(site - preference group - patient number)**	__ __ / __ __ __ / 2 0 __ __ dd mmm yyyy

Discharge Details	
Discharge Disposition	☐ Discharged Home ☐ Admitted ☐ Other, _____
Date and Time of Discharge	_____/_____/_____ dd mmm yyyy _____:_____ (24 hour clock)
Length of Stay in ED (calculated field):	_____ (hours, to one decimal place)
Final diagnosis at discharge (per MD):	
Radiologic Exams:	☐ Yes ☐ No
If yes, Date and Time of Radiologic Exam:	_____/_____/_____ dd mmm yyyy _____:_____ (24 hour clock)
Final diagnosis from radiologist's report: (*From chart or electronic health care system)*	

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REB # :	Study ID	Enrolment Date
PI: Dr. Samina Ali	____ ____ ____ - ____ - ____ ____ ____ **(site - preference group - patient number)**	__ __ / __ __ __ / 2 0 __ __ dd mmm yyyy

Follow-up Survey # 1 (1-3 days after discharge)

Call must be done in this time window

24 hours from discharge: _____:_____ (24 hour clock) Date: _____/_____/_____
dd mmm yyyy

72 hours from discharge: _____:_____ (24 hour clock) Date: _____/_____/_____
dd mmm yyyy

Follow-up Call Attempts:			
Number of call attempts made: ☐ 1 ☐ 2 ☐ 3 ☐ N/A – completed via email			
	Date and Time *(dd/ mmm/ yyyy HH:MM)*	**RA Initials**	**Comments**
Call # 1:	____/____/_____ ____:____		
Call # 2:	____/____/_____ ____:____		
Call # 3:	____/____/_____ ____:____		
24 hour Follow-up completed?: ☐ Yes ☐ No (Lost to follow-up)			
If YES, Continue…			

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REB # :	Study ID	Enrolment Date
PI: Dr. Samina Ali	____ ____ ____ - ____ - ____ ____ ____ (site - preference group - patient number)	__ __ / __ __ __ / 2 0 __ __ dd mmm yyyy

24 Hour Follow-up Survey

Adverse Effects and Side Effects	
After you were discharged from the emergency department, has your child experienced any adverse (bad) effects or side effects that you think are related to the pain medicines they got in the study? If YES, please explain:	☐ Yes ☐ No _____

Medication Uses	
After you were discharged from the emergency department, has your child taken any other medicines? If YES, please specify:	☐ Yes ☐ No _____

Home Pain Assessment	
Please rate your child's **overall** (average) pain experience in the last 24 hours, on a scale from 0-10, where 0=no pain and 10=the worst pain imaginable.	_____/10
Please rate your child's **worst** pain experienced in the last 24 hours, on a scale from 0-10, where 0=no pain and 10= the worst pain imaginable.	_____/10

Pain Related Function		
Did your child whine or complain more than usual in the last 24 hours?	☐ Yes	☐ No
Did your child play less than usual in the last 24 hours?	☐ Yes	☐ No
Did your child do the things they normally do in the last 24 hours?	☐ Yes	☐ No
Did your child act more quiet than usual in the last 24 hours?	☐ Yes	☐ No
Did your child have less energy than usual in the last 24 hours?	☐ Yes	☐ No
Did your child eat less than usual in the last 24 hours?	☐ Yes	☐ No
Did your child sleep less than usual in the last 24 hours?	☐ Yes	☐ No

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REB # :	Study ID	Enrolment Date
PI: Dr. Samina Ali	____ ____ ____ - ____ - ____ ____ ____ (site - preference group - patient number)	__ __ / __ __ __ / 2 0 __ __ dd mmm yyyy

Did your child hold the sore part of the body in the last 24 hours?	☐ Yes ☐ No
Did your child moan or groan more than usual in the last 24 hours?	☐ Yes ☐ No
Did your child want to be close to you more than usual in the last 24 hours?	☐ Yes ☐ No
Total PPPM Score (Automatic Calculation – Hidden Field) =	0 - 10

Activity Score	
Rate your child's ability to perform their usual activities:	☐ A No limitation ☐ B Mild limitation ☐ C Severe limitation

At-Home Treatments	
Did your child use any of the following in the last 24 hours to help treat their pain?	
Ice?	☐ Yes ☐ No
Elevation (raising their sore body part)?	☐ Yes ☐ No
Distraction (such as iPad, movies, games)?	☐ Yes ☐ No
Please describe any other things that your child used to help treat the pain.	Free text

Missed School and Work	
Did your child miss school and/or work in the last 24 hours?	☐ Yes ☐ No
Did YOU (caregiver/parent) miss work in the last 24 hours?	☐ Yes ☐ No

What Did Your Child Receive?
"We would like to let you know that your child received the following as their study drugs: [**A**dvil only OR **A**dvil and Tylenol OR **A**dvil and **D**ilaudid]. We will ask you about your thoughts in this when we email/ call you again in one week."

Do you have any other comments or concerns?
Thank you for completing this follow-up survey, we appreciate your participation in the No OUCH study! Without families like you, our research would not be possible. Your next (and last) follow-up survey will be in approximately 1 week.

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REB # :	Study ID	Enrolment Date
PI: Dr. Samina Ali	____ ____ ____ - ____ - ____ ____ ____ (site - preference group - patient number)	__ __ / __ __ __ / 2 0 __ __ dd mmm yyyy

Follow-up Survey # 2 (1-2 weeks after discharge)

Call must be done in this time window

1 week from discharge: Date: _____/_____/_____
dd mmm yyyy

2 weeks from discharge: Date: _____/_____/_____
dd mmm yyyy

Follow-up Call Attempts:			
Number of call attempts made: ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ N/A – completed via email			
	Date and Time *(dd/ mmm/ yyyy HH:MM)*	**RA Initials**	**Comments**
Call # 1:	____/____/_____ ____:____		
Call # 2:	____/____/_____ ____:____		
Call # 3:	____/____/_____ ____:____		
Call # 4:	____/____/_____ ____:____		
Call # 5:	____/____/_____ ____:____		
1 week Follow-up completed?: ☐ Yes ☐ No (Lost to follow-up)			
If YES, Continue…			

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REB # :	Study ID	Enrolment Date
PI: Dr. Samina Ali	____ ____ ____ - ____ - ____ ____ ____ (site - preference group - patient number)	__ __ / __ __ __ / 2 0 __ __ dd mmm yyyy

1-2 Week Follow-up Survey

Parent / Caregiver Satisfaction and Comfort Measures	
As you might remember, your child received _XXX__ in the emergency department, as part of this study. Did knowing what pain medicine(s) your child received in the study affect how you treated your child's pain at home?	☐ Yes ☐ No ☐ Unsure
Please explain:	Free text
How do you feel about the pain treatment provided by the medicines your child was given in the emergency department, as part of this study?	☐ Very Satisfied ☐ Somewhat Satisfied ☐ Neutral ☐ Somewhat dissatisfied ☐ Very dissatisfied
Please explain:	Free text
Do you feel that that the medicines that your child received in the emergency department, as part of this study provided adequate/ enough pain relief for your child?	☐ Yes ☐ No ☐ Unsure
Please explain:	Free text
Would you accept the same medicine for your child, in the unlikely event of a similar injury in the future?	☐ Yes ☐ No ☐ Unsure
Please explain:	Free text

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REB # :	Study ID	Enrolment Date
PI: Dr. Samina Ali	____ ____ ____ - ____ - ____ ____ ____ (site - preference group - patient number)	__ __ / __ __ __ / 2 0 __ __ dd mmm yyyy

Since visiting the emergency department, has your child had contact with any of the following health services for any reason related to their injury:	
A. Family Doctor / General Practitioner? If YES, how many times?	☐ Yes ☐ No _____ times
B. Orthopedic Specialist? If YES, how many times?	☐ Yes ☐ No _____ times
C. Revisit to Emergency Department? If YES, how many times?	☐ Yes ☐ No _____ times
D. Other Health Professional (e.g. physiotherapist, chiropractor, naturopath, rehabilitation professional, etc)? If YES, please specify which kind of professional If YES, how many times?	☐ Yes ☐ No Open text _____ times

For any health care visits related to this injury (including your original visit to the emergency department), has your family:	
A. Driven yourself or been given a lift in someone else's car?	☐ Yes ☐ No
If YES, how many times?	_____ times
If YES, estimated total cost of gas	_____$
If YES, did you use paid parking?	☐ Yes ☐ No
If YES, estimated total cost of parking	_____$
B. Used Public Transport (e.g. bus, subway)?	☐ Yes ☐ No
If YES, how many times?	_____ times
If YES, estimated total cost of using public transportation	_____$
C. Used Taxi/Uber rides?	☐ Yes ☐ No
If YES, how many times?	_____ times
If YES, estimated total cost of using this service	_____$

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REB # :	Study ID	Enrolment Date
PI: Dr. Samina Ali	____ ____ ____ - ____ - ____ ____ ____ (site - preference group - patient number)	__ __ / __ __ __ / 2 0 __ __ dd mmm yyyy

Additional Childcare Expenses	
A. Have you needed extra childcare for ANY of your children because of this injury (e.g. emergency department visit, other healthcare visits, child unable to go to school, etc)?	☐ Yes ☐ No
B. If YES, was it extra **unpaid** childcare (i.e. grandparents, neighbours) If YES, how many hours?	☐ Yes ☐ No _____ hours
C. If YES, was it extra **paid** childcare (i.e. babysitter, daycare)? If YES, how many hours? If YES, estimated total cost of for extra paid childcare	☐ Yes ☐ No _____ hours _____$

Since your emergency department visit ~1 week ago:	
How many days in total did your child use a pain medication, for injury-related pain?	_____ days
How many days in total did your child miss school and/ or work?	_____ days
How many days in total did your child not eat properly?	_____ days
How many nights in total did your child have disrupted/upset sleep?	_____ nights
How many days in total was your child unable to participate in their usual activities?	_____ days
How many days in total did YOU (or another caregiver) have to miss work from paid employment because of your child's injury?	_____ days
On a scale of 0 to 10 (where 0 means not at all affected and 10 means extremely affected), how much did this injury affect <u>your child's</u> quality of life?	0-10 numerical value
On a scale of 0 to 10 (where 0 means not at all affected and 10 means extremely affected), how much did this injury affect <u>your</u> quality of life?	0-10 numerical value

<u>Do you have any additional comments or concerns about how this injury and the pain medicines that you used affected you or your child's quality of life?</u>

Thank you for completing this final follow-up survey, we appreciate your participation in the No OUCH study! Without families like you, our research would not be possible.

A study of Non-Steroidal Or Opioid Analgesia Use for Children with Musculoskeletal Injuries: The No OUCH Trials

REB # :	Study ID	Enrolment Date
PI: Dr. Samina Ali	____ ____ ____ - ____ - ____ ____ ____ (site - preference group - patient number)	__ __ / __ __ __ / 2 0 __ __ dd mmm yyyy

CONCOMITANT AND RESCUE MEDICATIONS

Was a **rescue medication** given during the child's visit?	☐ Yes	☐ No
Were any other concomitant medications (other than the study drugs) given **during** the child's visit?	☐ Yes	☐ No
Were any concomitant medications given **after the child's** ED visit?	☐ Yes	☐ No

CONCOMITANT AND RESCUE MEDICATIONS							
Medication Name	**Indication**	**Rescue Medication? (Y/N)**	**Start Date & Time dd/mmm/yyyy HH:MM**	**Stop Date & Time dd/mmm/yyyy HH:MM (or Ongoing)**	**Dose**	**Route**	**Frequency**

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REB # :	Study ID	Enrolment Date
PI: Dr. Samina Ali	____ ____ ____ - ____ - ____ ____ ____ (site - preference group - patient number)	__ __ / __ __ __ / 2 0 __ __ dd mmm yyyy

ADVERSE EVENTS FORM

To be filled out by Research Nurse								To be filled out by Site Investigator			
No.	**Initial Report or Follow-up**	**Brief Description of Event**	**Onset Date & Time (dd/mmm/yyyy HH:MM)**	**Intensity grade:** 1. Mild 2. Moderate 3. Severe 4. Life-threatening 5. Fatal or Death	**Expected AE? Y / N**	**SAE? Y / N** **If YES, fill out SAE Form**	**Action Taken** 1. None 2. Medication 3. New or Prolonged Hospitalization 4. Procedure / Surgery 5. Other, specify	**Outcome** 1. Resolved 2. Resolved w/ sequalae 3. Ongoing 4. Death 5. Lost to f/u	**Date & Time Resolved (dd/mmm/yyyy HH:MM)**	**Relationship to Study** 1. Unrelated 2. Unlikely 3. Possible 4. Probable 5. Definite	**Site PI Initial**

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REB # :	Study ID	Enrolment Date
PI: Dr. Samina Ali	____ ____ ____ - ____ - ____ ____ ____ **(site - preference group - patient number)**	__ __ / __ __ __ / 2 0 __ __ dd mmm yyyy

SERIOUS ADVERSE EVENTS FORM

Date and time Site Investigator and Site Research Coordinator were notified: *(to be completed by Research Nurse)*	_____/_____/_____ _____:_____ dd mmm yyyy (24 hour clock)
To be completed by site RC / Investigator	
Date and time the local REB was notified:	_____/_____/_____ _____:_____ dd mmm yyyy (24 hour clock) ☐ Not applicable *Local SAEs must be reported to REB if the event is serious, unexpected, **and** considered to be related or possibly related to the study. Local SAEs are to be reported to the REB (via email to REB coordinator) within 7 days of their discovery*
Date and time the lead site Principal Investigator was notified:	_____/_____/_____ _____:_____ dd mmm yyyy (24 hour clock)
Follow up comments: *(to be completed by site Investigator)*	

Signature of Research Nurse: _____ Signature of Site Investigator: _____

Date: ___/_____/_____ Date: ___/_____/_____
dd mmm yyyy dd mmm yyyy

Ali S, *et al. BMJ Open* 2020; 10:e035177. doi: 10.1136/bmjopen-2019-035177

Two Randomized Controlled Trials of Non-Steroidal Or Opioid Analgesia Use for Children with Musculoskeletal Injuries: The No OUCH Study

REB # :	Study ID	Enrolment Date
PI: Dr. Samina Ali	____ ____ ____ - ____ - ____ ____ ____ (site - preference group - patient number)	__ __ / __ __ __ / 2 0 __ __ dd mmm yyyy

PROTOCOL DEVIATION FORM

Did any Protocol Deviations Occur? ☐ Yes ☐ No

Description of Protocol Deviation	Deviation Category/ Code*	Date Deviation Occurred (dd/mm/yyyy)	Time Deviation Occurred (HH:MM)	Date REB Notified (if applicable) (dd/mm/yyyy)	Date Sponsor Notified (if applicable) (dd/mm/yyyy)	Site PI Initial
1)				☐ Not applicable	☐ Not applicable	
2)				☐ Not applicable	☐ Not applicable	
3)				☐ Not applicable	☐ Not applicable	
4)				☐ Not applicable	☐ Not applicable	
5)				☐ Not applicable	☐ Not applicable	

Two Randomized Controlled Trials of Non-Steroidal Or Opioid Analgesia Use for Children with Musculoskeletal Injuries: The No OUCH Study

REB # :	Study ID	Enrolment Date
PI: Dr. Samina Ali	**____ ____ ____ - ____ - ____ ____ ____** **(site - preference group - patient number)**	__ __ / __ __ __ / 2 0 __ __ dd mmm yyyy

***DEVIATION CATEGORIES / CODES:**

Safety (Category A)
1. Not reporting an SAE within 72 hours
2. AE/SAE is not reported to IRB

Informed Consent (Category B)
3. Failure to obtain informed consent
4. Consent form used was not current REB-approved version Consent form missing
5. Consent form missing
6. Consent form not signed and dated by participant
7. Consent form does not contain all required signatures

Eligibility (Category C)
8. Participant did not meet eligibility criterion
9. Randomization of an ineligible participant
10. Participant randomized prior to completing Baseline Assessment, etc.

Protocol implementation (Category D)
11. Failure to keep IRB approval up to date
12. Participant receives wrong treatment
13. Use of unallowable concomitant treatments
14. Prescribed dosing outside protocol guidelines
15. Missed assessment
16. Assessment completed outside of protocol guidelines for timing

Other
17. Other, specify in log

A study of Non-Steroidal Or Opioid Analgesia Use for Children with Musculoskeletal Injuries: The No OUCH Trials

REB # :	Study ID	Enrolment Date
PI: Dr. Samina Ali	____ ____ ____ - ____ - ____ ____ ____ (site - preference group - patient number)	__ __ / __ __ __ / 2 0 __ __ dd mmm yyyy

Unanticipated Problems (UP) Form

Date UP Identified:	_____/_____/_____ dd mmm yyyy
Identify UP: *(Give the UP a brief title)*	Open text
The Unanticipated Problem was unexpected in terms of nature, severity or frequency:	☐ Yes ☐ No
The Unanticipated Problem is possibly related to participation in the research:	☐ Yes ☐ No
The Unanticipated Problem suggests that the research places subjects or others at a greater risk of harm than was previously known or recognized:	☐ Yes ☐ No
Briefly Describe the UP: *(Include additional or supplementary information as necessary. Include date of incident, date of discovery, describe harm or potential harm that occurred to subject(s), whether the incident is resolved, whether the subject(s) remains on study)*	Open text
What action was taken with the study as a result of the Unanticipated Problem? *(Check all that apply)*	☐ No action ☐ Revise protocol to eliminate apparent immediate hazards to subjects ☐ Modification of inclusion or exclusion criteria to mitigate newly identified risks ☐ Implementation of additional procedures for monitoring subjects ☐ Suspension of enrollment of new subjects ☐ Notify currently enrolled subjects ☐ Suspension of research procedures in currently enrolled subject ☐ Modification of consent documents to include a description of newly recognized risks (site and/or study wide)

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REB # :	Study ID	Enrolment Date
PI: Dr. Samina Ali	____ ____ ____ - ____ - ____ ____ ____ **(site - preference group - patient number)**	__ __ / __ __ __ / 2 0 __ __ dd mmm yyyy

	☐ Provision of additional information about newly recognized risks to previously enrolled subjects ☐ Other: _____
Is the Unanticipated Problem a serious adverse event?	☐ Yes ☐ No *If the Unanticipated Problem is a serious adverse event, submit this form and make sure that the adverse event form and Serious Adverse Event report have been completed and submitted as per local site policy.*
Was the Unexpected Problem reported to the sponsor?	☐ Yes ☐ No
If YES, Date UP reported to the sponsor:	_____/_____/_____ dd mmm yyyy
If NO, why was the UP not reported to the sponsor?	Open text
Was the Unexpected Problem reported to the local REB?	☐ Yes ☐ No
If YES, Date UP reported to the REB:	_____/_____/_____ dd mmm yyyy
If NO, why was the UP not reported to the REB?	Open text

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REB # :	Study ID	Enrolment Date
PI: Dr. Samina Ali	____ ____ ____ - ____ - ____ ____ ____ (site - preference group - patient number)	__ __ / __ __ __ / 2 0 __ __ dd mmm yyyy

Early Withdrawal Form

Did participant withdraw from the study?	☐ Yes ☐ No
If YES: Date of Discontinuation:	_____/_____/_____ dd mmm yyyy
Reasons for Discontinuation:	☐ Adverse Event / Serious Adverse Event ☐ Death ☐ Withdrawal of Consent / Assent ☐ Protocol Violation, Specify _____ ☐ Other, Specify _____
If withdrew consent / assent: 1. Permission to use collected data? 2. Permission to conduct Chart Review? 3. Telephone follow up to continue?	☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No
Comments:	

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