Protocol for PROcalcitonin and NEWS2 evaluation for Timely identification of sepsis and Optimal use of antibiotics in the emergency department (PRONTO): a multicentre open label randomised controlled trial

Supplementary File

Supplementary table 1 – Tiered Consent Levels

1	Information collected as part of the trial and data from medical records up to this point can be used in the trial
2	Data from records can be collected for the 90 days of the study
3	Participant or their consultee agree to be contacted at day 28 and day 90 to ask about health, wellbeing and any further medical treatment the participant may have received
4	Information collected as part of this trial can be used in other future studies which have been approved by appropriate NHS procedures (data linkage)
5	Participant or their consultee agree to be invited to an interview about my health experiences, my views on treatment, and what it was like to take part in the PRONTO trial.

PROcalcitonin and NEWS2 evaluation for Timely identification of sepsis and Optimal use of antibiotics in the Emergency Department

Site ID | | | | **PID** | | | | |

PARTICIPANT CONSENT FORM

Chief Investigator: Professor Neil French, University of Liverpool

(Please **initial** each statement and sign in full at the bottom of the page)

1.	I confirm that I have read and understood the Patient Information Sheet (version 1.2, dated 08.10.2020) for the PRONTO trial. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	_____
2.	I understand that I have already entered the trial but do not have to continue to take part. I understand that I can agree to take part in different parts of the trial and will indicate my choice below. I understand that I am free to withdraw my consent at any time, without giving any reason, without my normal medical care or legal rights being affected.	_____
3.	I understand the trial is randomised and no one has picked which treatment I received. I understand that I was randomised to have either an additional procalcitonin test or standard care. If I was allocated to the treatment arm of the trial, procalcitonin levels in my blood were tested as part of routine blood tests or via an additional finger prick in the absence of routine blood collection. I consent to the data generated from the procalcitonin test to be used for the purposes of this trial.	_____
4.	I understand that information collected during the trial can be used by the study team to look at treatment of sepsis in patients presenting to the emergency department.	_____
5.	I understand that information collected about me that is held and maintained by NHS Digital and other central UK NHS bodies, may be collected from my medical records and other health-related records and looked at by the research team and responsible practitioners during the trial.	_____
6.	I understand that information collected about me (including name and address) will be held at the Centre for Trials Research, Cardiff University according to the 2018 General Data Protection Regulation (GDPR) (EU 2016/679). I understand that this information will be kept strictly confidential and that no personal information will be used in the study report or publications.	_____
7.	I agree to continue to take part in the trial. **Please select which aspects you agree to take part in:**	_____
8	I agree that information collected as part of the trial and data from my medical records up to this point can be used in the trial.	_____
9	I agree that data from my records can be collected for the 90 days of the study	_____

10	I agree to be contacted at day 28 and day 90 to ask about my health, wellbeing and any further medical treatment I may have received. I give my consent for a member of the research team to contact me by the following methods to complete these surveys: Telephone Email Post.	
11	I agree that the information collected as part of this trial can be used in other future studies which have been approved by appropriate NHS procedures (data linkage)	
12.	I agree to be invited to an interview about my health experiences, my views on treatment, and what it was like to take part in the PRONTO trial.	

Name of Participant: _____ Signed:_____Date:___/___/___

Name of Person taking consent _____ Signed:_____Date:___/___/___

Supplementary Table 2: Outcome data collection

Outcome	Data Source	Type of data	Frequency	By Whom
Antibiotic (Abx) initiation	Observation (Obs) charts/medical notes/drug charts	Time of initiation, Abx type, dose, duration	Admission/Daily	Research Nurse
Abx use (IV and Oral) in-patient	Obs charts/medical notes/drug charts	Abx type, dose, duration	Daily	Research Nurse
Abx use (IV and Oral) post discharge up to 28 days	Obs charts/medical notes/drug charts/patient report/GP record	Abx type, dose, duration	At 28 day	Research Nurse
Adverse events	Obs charts/medical notes	Date, type	Daily	Research Nurse
ICU usage	Medical notes	Date, details of admission to ICU	Daily	Research Nurse
Unscheduled readmissions	Medical notes	ICU re-admissions, re-admissions post discharge	Daily	Research Nurse
Mortality	Medical notes	Date, Description	If before Day 90	Research Nurse
Discharge	Medical notes	Date, Description	If before Day 28	Research Nurse
Serious Adverse Drug Reactions (ADRs)	Medical notes	ADR(s)	Daily	Research Nurse
Health utility	Patient reported	-	Day 28 and Day 90	EQ-5D/5L, Patient reported questionnaire, collected by telephone or by post
Health-related Quality of Life (EQ-5D/5L)	Patient reported	-	Day 28 and Day 90	Patient reported, collected by telephone, or by post
Resource use	Patient reported	Direct medical costs and resource use	Day 28 and Day 90	Patient reported, collected by telephone, or by post