## **APPENDIX 3: Trial registration data set**

| Primary registry and trial identifying number  Date of registration in primary registry  Secondary identifying numbers  H-20009117 (The Ethics Committee of the Capital Region of Denmark)  Source(s) of monetary or material support  Copenhagen University Hospital Rigshospitalet  Primary sponsor  Copenhagen University Hospital Rigshospitalet,  Ulrikka Nygaard  N/A  Contact for public queries  Allan Bybeck Nielsen allan.bybeck.nielsen@regionh.dk  Allan Bybeck Nielsen allan.bybeck.nielsen@regionh.dk  Contact for scientific queries  Allan Bybeck Nielsen allan.bybeck.nielsen@regionh.dk  Public title  ORAL-ONLY ANTIBIOTICS FOR BONE AND JOINT INFECTIONS IN CHILDREN  Scientific title  ORAL-ONLY ANTIBIOTICS FOR BONE AND JOINT INFECTIONS IN CHILDREN  Countries of recruitment  Denmark  Health condition(s) or problem(s) studied  Intervention(s)  Standard: IV + oral antibiotic treatment vs. Experimental: Oral only antibiotic treatment.  Key inclusion and exclusion criteria  Inclusion:  - Age 3 months to 18 years - Antibiotic therapy for bone or joint infection. Exclusion:  - Severe disease at admission - Complicated bone or joint infection - Expected need of major surgery within the first 24 hours of treatment - Significant co-morbidities - Previous bone or joint infection - Expected need of major surgery within the first 24 hours of treatment - Significant co-morbidities - Previous bone or joint infection - Expected need of major surgery within the first 24 hours of treatment - Significant co-morbidities - Previous bone or joint infection - Expected need of major surgery within the first 24 hours of treatment - Significant co-morbidities - Previous bone or joint infection - Expected need of major surgery within the first 24 hours of treatment - Significant co-morbidities - Previous bone or joint infection - Expected need of major surgery within the first 24 hours of treatment - Significant co-morbidities - Previous bone or joint infection - Expected need of major surgery within the first - Previous bone or joint infection -  | DATA CATEGORY                                 | INFORMATION                                   |
|--|---|---|
| Secondary identifying numbers  | Primary registry and trial identifying number | ClinicalTrials.gov: NCT04563325               |
| Region of Denmark)  Cource(s) of monetary or material support  Copenhagen University Hospital Rigshospitalet  Primary sponsor  Copenhagen University Hospital Rigshospitalet, Ulrikka Nygaard  N/A  Contact for public queries  Allan Bybeck Nielsen allan.bybeck.nielsen@regionh.dk  Allan Bybeck Nielsen allan.bybeck.nielsen@regionh.dk  Public title  ORAL-ONLY ANTIBIOTICS FOR BONE AND JOINT INFECTIONS IN CHILDREN  Scientific title  ORAL-ONLY ANTIBIOTICS FOR BONE AND JOINT INFECTIONS IN CHILDREN  Countries of recruitment  Health condition(s) or problem(s) studied  Intervention(s)  Intervention(s)  Standard: IV + oral antibiotic treatment vs. Experimental: Oral only antibiotic treatment vs. Experimental: Oral only antibiotic treatment.  Key inclusion and exclusion criteria  Inclusion: - Age 3 months to 18 years - Antibiotic therapy for bone or joint infection. Exclusion: - Severe disease at admission - Complicated bone or joint infection. Exclusion: - Severe disease at admission - Complicated bone or joint infection. Expected need of major surgery within the first 24 hours of treatment - Significant co-morbidities - Previous bone or joint infection Antibiotic therapy for more than 24 hours before inclusion.  Study type  Open label, randomized 1:1, non-inferiority trial. Investigator of the primary endpoint is blinded to treatment allocation.  Date of first enrolment  Sep 2020  Target sample size 180  Proportion of children with sequelae 6 months after initiation of treatment defined as abnormal mobility or function of the affected joint/bone. Evaluated by blinded clinical examination by a qualified pediatrician and/or pediatric orthopedic surgeon.  Secondary outcomes   | Date of registration in primary registry      | 18th September 2020                           |
| Copenhagen University Hospital Rigshospitalet  | Secondary identifying numbers                 |   |
| Primary sponsor  Secondary sponsor(s)  N/A  Contact for public queries  Allan Bybeck Nielsen allan.bybeck.nielsen@regionh.dk  Contact for scientific queries  Allan Bybeck Nielsen allan.bybeck.nielsen@regionh.dk  Contact for scientific queries  Allan Bybeck Nielsen allan.bybeck.nielsen@regionh.dk  Public title  ORAL-ONLY ANTIBIOTICS FOR BONE AND JOINT INFECTIONS IN CHILDREN  Scientific title  ORAL-ONLY ANTIBIOTICS FOR BONE AND JOINT INFECTIONS IN CHILDREN - A nationwide randomized open-label non-inferiority trial.  Denmark  Health condition(s) or problem(s) studied  Antibiotic treatment of bone and joint infections in children and adolescents  Intervention(s)  Standard: IV+ oral antibiotic treatment vs. Experimental: Oral only antibiotic treatment.  Key inclusion and exclusion criteria  Inclusion:  - Age 3 months to 18 years  - Antibiotic therapy for bone or joint infection. Exclusion:  - Severe disease at admission  - Complicated bone or joint infection.  Exclusion:  - Severe disease at admission  - Complicated bone or joint infection.  Exclusion:  - Severe disease at admission  - Complicated bone or joint infection.  Exclusion:  - Severe disease at admission  - Complicated bone or joint infection.  Exclusion:  - Severe disease at admission  - Complicated bone or joint infection.  Exclusion:  - Severe disease at admission  - Complicated bone or joint infection.  Exclusion:  - Severe disease at admission  - Complicated bone or joint infection.  Exclusion:  - Severe disease at admission  - Complicated bone or joint infection.  Exclusion:  - Severe disease at admission  - Complicated bone or joint infection.  Exclusion:  - Severe disease at admission  - Complicated bone or joint infection.  Exclusion:  - Severe disease at admission  - Complicated bone or joint infection.  Exclusion:  - Severe disease at admission  - Complicated bone or joint infection.  Exclusion:  - Severe disease at admission  - Complicated bone or joint infection.  Exclusion:  - Severe disease at admission  - Complicated bone or joint infection |   |   |
| Secondary sponsor(s)  N/A  Contact for public queries  Allan Bybeck Nielsen allan.bybeck.nielsen@regionh.dk  Allan Bybeck Nielsen allan.bybeck.nielsen@regionh.dk  Allan Bybeck Nielsen allan.bybeck.nielsen@regionh.dk  Public title  ORAL-ONLY ANTIBIOTICS FOR BONE AND JOINT INFECTIONS IN CHILDREN  Scientific title  ORAL-ONLY ANTIBIOTICS FOR BONE AND JOINT INFECTIONS IN CHILDREN - A nationwide randomized open-label non-inferiority trial.  Denmark  Health condition(s) or problem(s) studied  Antibiotic treatment of bone and joint infections in children and adolescents  Intervention(s)  Standard: IV + oral antibiotic treatment vs. Experimental: Oral only antibiotic treatment.  Key inclusion and exclusion criteria  Inclusion: - Age 3 months to 18 years - Antibiotic therapy for bone or joint infection. Exclusion: - Severe disease at admission - Complicated bone or joint infection - Expected need of major surgery within the first 24 hours of treatment - Significant co-morbidities - Previous bone or joint infection Antibiotic therapy for more than 24 hours before inclusion.  Study type  Open label, randomized 1:1, non-inferiority trial. Investigator of the primary endpoint is blinded to treatment allocation.  Date of first enrolment - Sep 2020 - Target sample size - 180 - Recruitment status - Recruiting - Primary outcome - Proportion of children with sequelae 6 months after initiation of treatment defined as abnormal mobility or function of the affected joint/bone. Evaluated by blinded clinical examination by a qualified pediatrician and/or pediatric orthopedic surgeon Non acute treatment failure   | Source(s) of monetary or material support     | Copenhagen University Hospital Rigshospitalet |
| Secondary sponsor(s)   N/A   | Primary sponsor                               |   |
| Contact for public queries  Allan Bybeck Nielsen allan.bybeck.nielsen@regionh.dk  Allan Bybeck Nielsen allan.bybeck.nielsen@regionh.dk  Public title  ORAL-ONLY ANTIBIOTICS FOR BONE AND JOINT INFECTIONS IN CHILDREN  Scientific title  ORAL-ONLY ANTIBIOTICS FOR BONE AND JOINT INFECTIONS IN CHILDREN - A nationwide randomized open-label non-inferiority trial.  Denmark  Health condition(s) or problem(s) studied Antibiotic treatment of bone and joint infections in children and adolescents  Intervention(s)  Standard: IV + oral antibiotic treatment vs. Experimental: Oral only antibiotic treatment.  Key inclusion and exclusion criteria  Inclusion: - Age 3 months to 18 years - Antibiotic therapy for bone or joint infection. Exclusion: - Severe disease at admission - Complicated bone or joint infection - Expected need of major surgery within the first 24 hours of treatment - Significant co-morbidities - Previous bone or joint infection Antibiotic therapy for more than 24 hours before inclusion.  Study type  Open label, randomized 1:1, non-inferiority trial. Investigator of the primary endpoint is blinded to treatment allocation.  Date of first enrolment  Sep 2020  Target sample size 180  Recruitment status Recruitment status Recruitment status Primary outcome  Proportion of children with sequelae 6 months after initiation of treatment defined as abnormal mobility or function of the affected joint/bone. Evaluated by blinded clinical examination by a qualified pediatrician and/or pediatric orthopedic surgeon.  Secondary outcomes   |   |   |
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| Denmark  |   |   |
| Health condition(s) or problem(s) studied   Antibiotic treatment of bone and joint infections in children and adolescents  | Countries of recruitment                      |   |
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| qualified pediatrician and/or pediatric orthopedic surgeon.  Secondary outcomes - Non acute treatment failure  |   | ·   |
| surgeon. Secondary outcomes - Non acute treatment failure  |   | · · · · · · · · · · · · · · · · · · ·         |
|  |   |   |
| ·  | Secondary outcomes                            | - Non acute treatment failure                 |
|  |   | - Recurrent infection                         |