

APPENDIX 3: Trial registration data set

DATA CATEGORY	INFORMATION
Primary registry and trial identifying number	ClinicalTrials.gov: NCT04563325
Date of registration in primary registry	18th September 2020
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
Secondary sponsor(s)	N/A
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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.
Countries of recruitment	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.
Secondary outcomes	- Non acute treatment failure - Recurrent infection