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Diagnostics, monitoring, and shortening of the treatment of acute haematogenous OsteoMyelitis and Septic Arthritis of childhood

Submission date	Recruitment status
04/01/2007	No longer recruiting
Registration date	**Overall study status**
26/02/2007	Completed
Last Edited	**Condition category**
09/03/2011	Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1

Study information

Scientific Title

Acronym
OM-SA

Study objectives
Current treatment of acute paediatric osteoarticular infections can be considerably shortened and otherwise simplified.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Protocol approved by the Ethical Committees of the participating centres (Central Hospital of Päijät-Häme on March 7, 1983, Jorvi Hospital on May 30, 1983, and Helsinki University Hospital on July 25, 1983)

Study design
Prospective, randomized, noninferiority trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Acute bacterial osteoarticular infection of children

Interventions
Computer-generated list divided patients to receive a long (30 days), or a short (20 days for osteomyelitis, 10 days for septic arthritis) medication. Children being born on an odd day received clindamycin, those born on an even day received first generation cephalosporin. Antimicrobial was given intravenously only for two to four days, the treatment being completed orally. No serum assays were performed. Surgery was kept as minimum, its aim being mainly to obtain an adequate sample for bacteriology.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Clindamycin, cephalosporin

Primary outcome measure
Success rate at least one year post-hospitalization. Failure was defined as a case in which treatment for an osteoarticular infection was reinstituted within one year.

Secondary outcome measures
All potential defects in the affected bone or joint which, according to the treating paediatrician or orthopaedic surgeon, were likely to leave a residual defect with potential malfunction.

Overall study start date
01/01/1983

Completion date
01/01/2003

Eligibility

Key inclusion criteria
Children aged between three months to 14 years with bacteriologically proven acute haematogenous osteomyelitis, septic arthritis, or their combination

Participant type(s)
Patient

Age group
Child

Lower age limit
3 Months

Upper age limit
14 Years

Sex
Both

Target number of participants
At least 63 in each arm

Key exclusion criteria
1. Immunocompromized
2. Other underlying diseases
3. Previous osteoarticular infection

Date of first enrolment
01/01/1983

Date of final enrolment
01/01/2003

Locations

Countries of recruitment
Finland

Study participating centre
Hospital District of Helsinki and Uusimaa
Helsinki
Finland
00029

Sponsor information

Organisation
HUCH Hospital for Children and Adolescents, University of Helsinki (Finland)

Sponsor details
PO Box 281
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/02e8hzf44

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
HUCH Hospital for Children and Adolescents, University of Helsinki (Finland)

Funder Name
Orion Pharma Ltd (Finland) - decision on funding pending

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2010		Yes	No