

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

Submission date
04/01/2007

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
26/02/2007

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
09/03/2011

Condition category
Infections and Infestations

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Helsinki

Finland

00029

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