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A national feasibility study for children's bone and joint infections

Submission date
08/11/2012

Recruitment status
No longer recruiting

Registration date
12/11/2012

Overall study status
Completed

Last Edited
18/01/2019

Condition category
Infections and Infestations

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

Plain English summary of protocol

Background and study aims
Bone and joint infections in children are relatively uncommon. The collective term for them is osteoarticular infections or OAI. They need to be treated promptly and effectively in order to prevent long term damage. Currently there is no national agreement amongst doctors regarding the best way to treat these infections. Usually children with bone and joint infections are treated with antibiotics given into a vein, known as intravenous or IV antibiotics, followed by oral antibiotics. What we do not know is how long it is necessary to give intravenous antibiotics before it is safe to switch to oral antibiotics. IV antibiotics also have risks, such as infection of the veins because of the lines used to give the antibiotics. These risks are reduced by shortening the duration of IV antibiotics. Oral antibiotics can be taken at home, reducing the length of hospital stay. This study aims to ascertain the spectrum and severity of bone and joint infections in children in the UK. We will also collect information on how different hospitals investigate and treat these infections both with antibiotics and with surgery where necessary. After this we aim use the information to see if it is possible to do a study looking at shorter courses of IV antibiotics for these infections, using this database as a guide.

Who can participate?
All children aged between 3 months and 16-years-old presenting to participating hospitals during a 6 month period with a diagnosis of bone or joint infection will be included in this database, unless they request that their data is not entered.

What does the study involve?
The database will be advertised using posters on wards at participating centres. Patient data will be entered via web-based forms into the database by research doctors and nurses at these centres.
At 5 specific centres additional tests will also be done and linked to the database. A test called polymerase chain reaction (PCR) looking for bacterial DNA in samples routinely taken from patients with bone and joint infection will also be tested. This test shows what bugs are causing the infection more often than techniques such as trying to grow bacteria, which is the current method. It may therefore allow treatment to be focused and rationalised and also identify bacteria that are resistant or more likely to cause complications. We will also be doing this test on a throat swab taken from children at these centres to see if they carry the bacteria causing

the OAI in their throat. At the 5 centres participating in PCR patients and their parents will also be asked for consent for an additional blood sample to be taken at a time when routine bloods are being done. This sample will be used to look for particular genes involved in the immune system, and the proteins they produce in response to infection.

What are the possible benefits and risks of participating?
There will be no direct benefit to the patient of being in the study. PCR results and blood results will not be done in real time, and will therefore not be available to affect the patients treatment. There are also no risks associated with participating in this study as it is a service evaluation, and additional samples are non-invasive.

Where is the study run from?
University Hospital Southampton NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
February 2013 to July 2013

Who is funding the study?
UK NIHR Health Technologies Assessment Programme

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 10/146/01

Study information

Scientific Title
Duration of intravenous antibiotic therapy for children with acute osteomyelitis or septic arthritis: a feasibility study

Study objectives
Currently there is no international & little UK consensus regarding the route or duration of antibiotic treatment for acute OM/SA in children. To assess the feasibility of an RCT to determine the safety of early oral switch from IV therapy, it isessential to also gain information to determine the total length of therapy to be used in a trial. If this study determines an RCT is not feasible, this data will allow us to produce a national consensus guideline derived from the clinician survey. In stage 1, we aim to conduct a service evaluation of OM/SA in children 1 month (lower limit of clindamycin licence) to 16 years including routine micro & additional new molecular test. In stage 2 we will evaluate the feasibility of performing an RCT (as above). By assessing case spectrum & current NHS practice, we will gain consensus on the proposed trial total duration of therapy.
This study will canvas consumers & clinical stakeholders to report on:
1. Current case load, disease spectrum & clinical practice in the diagnosis & treatment of OM/SA in secondary & tertiary UK care
2. Feasibility of performing targeted molecular tests on routinely collected samples sent to a HPA Regional Lab
3. Feasibility of carrying out an RCT into antimicrobial therapy route & duration in paediatric acute OM/SA. This will be achieved by obtaining qualitative & quantitative data on:
3.1. Willingness of clinicians to randomise to proposed protocol
3.2. Willingness of patients & parents to be randomised
3.3. No of patients seen
3.4. Clinical stakeholder & consumer perception of relevant outcomes
3.5. Identification of non-inferiority margins of acceptable outcomes
3.6. Likely RCT recruitment rates

More details can be found at: http://www.nets.nihr.ac.uk/projects/hta/1014601
Protocol can be found at: http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0016/81142/PRO-10-146-01.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Feasibility study with quantitative diagnostic and qualitative methods

Primary study design
Observational

Secondary study design

Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Paediatric bone or joint infection

Interventions
At the majority of participating centres' patient data will be entered into the database by the team looking after the patient or local research nurse. This will include patient demographics such as age, ethnicity and gender, dates of presentation to hospital, blood tests and imaging done, and treatment given. We will also collect the blood and microbiology results, reports of imaging and details of surgery.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Quantitative and qualitative data

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/02/2013

Completion date
31/07/2013

Eligibility

Key inclusion criteria
All children aged 3 months to 16 years presenting to participating hospitals within a 6 month period with a diagnosis of septic arthritis and/or osteomyelitis

Participant type(s)
Patient

Age group

Child

Lower age limit
3 Months

Upper age limit
16 Years

Sex
Both

Target number of participants
All children with condition at participating hospitals

Key exclusion criteria
1. Infants under 3 months, and adolescents over 16 years
2. Patients who request not to be included in the database

Date of first enrolment
01/02/2013

Date of final enrolment
31/07/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
NIHR Wellcome Trust Clinical Research Facility
Southampton
United Kingdom
SO16 6YD

Sponsor information

Organisation
University Hospital Southampton NHS Foundation Trust (UK)

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Sponsor type
Hospital/treatment centre

Website
http://www.uhs.nhs.uk/

ROR
https://ror.org/0485axj58

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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	01/09/2017		Yes	No