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Daptomycin > 6 mg/kg/day in complex bone and joint infection

Submission date	Recruitment status	[_] Prospectively registered
26/01/2016	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
28/01/2016	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
30/09/2016	Infections and Infestations	

Plain English summary of protocol

Background and study aims
Bone and joint infections (BJI) result from a host of different causes, can have very different symptoms and prognoses and need to be treated in different ways. Some, such as uncomplicated childhood osteomyelitis (a bone infection), can be very successfully treated with a short course of antibiotics. In contrast, in some situations such as chronic implant-associated BJI, the pathogen (agent causing the infection) is difficult to eradicate, meaning it is likely to come back despite surgery and prolonged intravenous antibiotic therapy (fed though a drip). In such cases, team-work in specialist hospitals (or tertiary care centers) is required to determine how best to treat the patient to avoid failure, long-lasting disability and risk of amputation. The choice of antimicrobial therapy is also challenging, due to bone diffusion (the antibiotic diffusing into bone tissue), having to use antibiotics that work against bacterial biofilms (that is, bacteria that can stick to surfaces, such as bone), antibiotic resistance and the high risk of severe adverse events (SAE) (side effects). Consequently, off-label use of recently developed antimicrobials, such as daptomycin, is frequently required as salvage therapy (therapy for a condition that doesn't respond to standard therapy) in complex BJI. This study looks at the safety of daptomycin and how successful it is at treating BJI.

Who can participate?
Adults with complex BJI.

What does the study involve?
Each participant is given high doses (>6 mg/kg/day) of daptomycin for as long as is deemed necessary but the physician. Each patient is then followed up to see if the treatment worked and whether they suffered any serious side effects.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Hospices Civils de Lyon (France)

When is the study starting and how long is it expected to run for?
January 2011 to July 2013

Who is funding the study?
Hospices Civils de Lyon (France)

Who is the main contact?
Professor Tristan Ferry

Contact information

Type(s)
Scientific

Contact name
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Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Daptomycin > 6 mg/kg/day in complex bone and joint infection: prospective cohort study in a regional reference center

Study objectives
Safety and efficacy of daptomycin in patients with complex bone and joint infection

Ethics approval required
Old ethics approval format

Ethics approval(s)
Committee for the Protection of Persons Sud Est III (CPP Sud Est III), ref: QH 20/2014

Study design
Cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Complex bone and joint infection

Interventions
A prescription of high doses (>6 mg/kg/day) of daptomycin for complex bone and joint infection. There is only one arm. The total duration is based on the physician decision, and the follow up is based on the usual clinical practice.

Intervention Type

Primary outcome measure
Rate of treatment failure that occurred either during the treatment of after the discontinuation of the treatment. Factors associated with treatment failure were determined on univariate Cox analysis and Kaplan-Meier curves.

Secondary outcome measures
Occurence of serious adverse events

Overall study start date
01/01/2011

Completion date
01/07/2013

Eligibility

Key inclusion criteria
Patients with complex BJI managed in the trial participating centre and for whom the need for a treament with daptomycin has been validated in a multidisciplinary meeting

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
43

Key exclusion criteria
N/A

Date of first enrolment
01/01/2011

Date of final enrolment
01/07/2013

Locations

Countries of recruitment
France

Study participating centre
Hospices Civils de Lyon
France
69004

Sponsor information

Organisation
Hospices Civils de Lyon

Sponsor details
Quai des Celestins
Lyon
France
69000

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01502ca60

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Hospices Civils de Lyon

Results and Publications

Publication and dissemination plan
The article has been accepted for publication in BMC Infectious Disease, but the editor would like us to register this trial before publication

Intention to publish date
29/02/2016

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	17/02/2016		Yes	No