

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

Submission date 26/01/2016	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 28/01/2016	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 30/09/2016	Condition category Infections and Infestations	<input type="checkbox"/> Individual participant data

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 through 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

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

Occurrence of serious adverse events

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 treatment with daptomycin has been validated in a multidisciplinary meeting

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

ROR

<https://ror.org/01502ca60>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Hospices Civils de Lyon

Results and Publications

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