

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

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

Prof Tristan Ferry

### Contact details

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Lyon

France

69004

## 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 or after the discontinuation of the treatment. Factors associated with treatment failure were determined on univariate Cox analysis and Kaplan-Meier curves.

**Secondary outcome measures**

Occurrence 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 treatment 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?
<a href="#">Results article</a>	results	17/02/2016		Yes	No