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A phase III, randomised, double blind, multicentre study to evaluate the safety and efficacy of dalbavancin versus linezolid in the treatment of complicated skin and soft tissue infections with suspected gram-positive bacterial pathogens

Submission date
30/09/2004

Recruitment status
No longer recruiting

Registration date
30/09/2004

Overall study status
Completed

Last Edited
30/08/2016

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number

N0123138529

Study information

Scientific Title
A phase III, randomised, double blind, multicentre study to evaluate the safety and efficacy of dalbavancin versus linezolid in the treatment of complicated skin and soft tissue infections with suspected gram-positive bacterial pathogens

Study objectives
To compare how safe the trial medication dalbavancin is when compared to a standard of care treatment in patients suffering from complicated skin infections

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Phase III randomised double blind multicentre study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Infections and Infestations: Gram-positive bacterial pathogens

Interventions
Dalbavancin vs standard care

Intervention Type
Other

Phase
Phase III

Primary outcome(s)
The clinical and microbiological responses to therapy.

Key secondary outcome(s))
Not provided at time of registration

Completion date
05/08/2004

Eligibility

Key inclusion criteria
1. Patients having infection consistent with complicated skin and soft tissue infection either involving deeper soft tissue or requiring significant surgical intervention
2. Patients to require 24hrs of parental therapy for suspected gram-positive complicated skin

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
30/09/2003

Date of final enrolment
05/08/2004

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University Hospitals of Leicester
Leicester
United Kingdom
LE1 4PW

Sponsor information

Organisation
Department of Health

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Hospitals of Leicester NHS Trust

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration