

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	☐ Prospectively registered
Registration date 30/09/2004	Overall study status Completed	☐ Protocol
Last Edited 30/08/2016	Condition category Infections and Infestations	☐ 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

Primary study design

Interventional

Study design

Phase III randomised double blind multicentre study

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