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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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
The clinical and microbiological responses to therapy.

Secondary outcome measures
Not provided at time of registration

Overall study start date
30/09/2003

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

Age group
Not Specified

Sex
Not Specified

Target number of participants
Not provided at time of registration

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
England

United Kingdom

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

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Hospitals of Leicester NHS Trust

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration