

Randomised controlled trial of the efficacy of adding intravenous benzylpenicillin to intravenous flucloxacillin in the treatment of lower limb cellulitis

Submission date

30/09/2004

Recruitment status

No longer recruiting

Registration date

30/09/2004

Overall study status

Completed

Last Edited

23/09/2009

Condition category

Skin and Connective Tissue Diseases

☐ Prospectively registered

☐ Protocol

☐ Statistical analysis plan

☒ Results

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

N0013101031

Study information

Scientific Title

Study objectives

Does the addition of benzylpenicillin shorten the duration of stay of patients and/or decrease the number of beta-lactam therapy failures.

Please note that as of 23/09/09 inclusion and exclusion criteria for this trial have been updated.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from local medical ethics committee

Primary study design

Interventional

Study design

Randomised double-blind placebo controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Cellulitis

Interventions

In non-penicillin allergic patients, after consent they will be randomised to receive one of 2 treatments:

1. Intravenous (IV) flucloxacillin 1g four times a day (qds) and IV benzylpenicillin 1.2 g qds
2. IV flucloxacillin 1g qds and IV placebo (N Saline) qds.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Duration of stay, as determined by the number of 6 hourly doses of antibiotic the patient received prior to discharge.

Key secondary outcome(s)

Therapy failure rate

Completion date

01/04/2003

Eligibility

Key inclusion criteria

Current information as of 23/09/09:

1. Patients with lower limb cellulitis and who require admission
2. Initial diameter of cellulitis >100 mm
3. Able to understand spoken and written english

Initial information at time of registration:

Patients with lower limb cellulitis and who require admission

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

Added 23/09/09:

1. Known allergy to the study drugs
2. Known renal or hepatic impairment,
3. Random capillary glucose >13 mmol/l
4. Acute co-existent illness in the affected leg, such as deep venous thrombosis, or wound/abscess requiring operative debridement/repair.

Date of first enrolment

01/10/2001

Date of final enrolment

01/04/2003

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Oral Medicine Department
London

United Kingdom
SE1 9RT

Sponsor information

Organisation

Department of Health

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Guy's and St Thomas' NHS Trust (UK)

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	01/05/2005		Yes	No