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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
[X] Results
[_] Individual participant data

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
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

Study design
Randomised double-blind placebo controlled trial

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

Secondary outcome measures
Therapy failure rate

Overall study start date
01/10/2001

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

Age group
Adult

Sex
Both

Target number of participants
81 (intervention group: 41, control group:40)

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
England

United Kingdom

Study participating centre
Oral Medicine Department
London
United Kingdom
SE1 9RT

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

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2005		Yes	No