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Randomised controlled trial to investigate whether prophylactic antibiotics can prevent further episodes of cellulitis (erysipelas) of the leg (PATCH II)

Submission date 11/10/2007	**Recruitment status** Stopped	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data [_] Record updated in last year
Registration date 06/12/2007	**Overall study status** Stopped	
Last Edited 01/05/2012	**Condition category** Skin and Connective Tissue Diseases	

Plain English summary of protocol
http://www.ctu.mrc.ac.uk/research_areas/study_details.aspx?s=90

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
26083

Study information

Scientific Title

A randomised controlled trial of phrophylactic antibiotics for the prevention of recurrent cellulitis (erysipelas) of the leg (PATCH II)

Acronym
PATCH II - Prophylactic Antibiotics for the Treatment of Cellulitis at Home II

Study objectives
To assess whether a period of six months of prophylactic penicillin after an episode of cellulitis of the leg reduces the risk of repeat episodes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Nottingham Research Ethics Committee (2) on 27/03/2006

Primary study design
Interventional

Study design
Multi-centre double-blind randomised controlled trial

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Cellulitis of the leg

Interventions
Penicillin VK 250 mg orally twice a day (b.d.) or placebo (b.d.) for 6 months.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Penicillin

Primary outcome(s)
Time to next episode of cellulitis. Follow-up duration for primary endpoint: up to 3 years depending on date of recruitment into the trial.

Key secondary outcome(s)
1. Proportion of participants with repeat episodes of cellulitis in the active treatment arm compared with the placebo treatment arm at the end of the treatment phase, and at the end of the non-intervention follow-up phase
2. Proportion of participants with oedema and/or ulceration in the active treatment arm compared with the placebo treatment arm at the end of the treatment phase, and at the end of

the non-intervention follow-up phase
3. Number of nights in hospital for the treatment of repeat episodes of cellulitis. Duration of follow-up: up to 3 years depending on date of recruitment into the trial.
4. Number of adverse drug reactions reported in each treatment arm. Duration of follow-up: up to 3 years depending on date of recruitment into the trial.
5. Cost-effectiveness, including GP consultations, prescriptions for antibiotics and days in hospital
6. Predictors of response multiple regression model to explore the impact of known risk factors in predicting the efficacy of prophylaxis
7. Impact of cellulitis on health-related quality of life, assessed using the EuroQol (EQ-5D) and also a measure specific to dermatology (the Dermatology Life Quality Index [DLQI]). These will be measured at baseline (i.e. during the index episode of cellulitis) and at 10 days. The same measures will also be taken during any repeat episodes of cellulitis.

Completion date
31/12/2010

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
Cellulitis of the leg

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Taken antibiotic prophylaxis (defined as more than 3 months usage) for the prevention of cellulitis within 6 months prior to index episode
2. A time lapse of longer than 12 weeks since the start of treatment for the index episode to the date of potential randomisation into the trial
3. Known allergy to penicillin
4. Preceding leg ulceration, surgery or penetrating trauma (NB: this does not exclude patients with toeweb maceration/tinea pedis or other minor/blunt wounds)
5. Treating physician or principal investigator unwilling to randomise patient
6. No access to a telephone
7. Aged less than 16 years
8. Unable to give informed consent
9. Already taking part in a research study

Date of first enrolment
01/01/2007

Date of final enrolment
31/12/2010

Locations

Countries of recruitment
United Kingdom

England

Ireland

Study participating centre
Department of Dermatology
Nottingham
United Kingdom
NG7 2UH

Sponsor information

Organisation
University of Nottingham (UK)

ROR
https://ror.org/01ee9ar58

Funder(s)

Funder type
Charity

Funder Name
The BUPA Foundation (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	01/01/2012		Yes	No
Other publications	discussion of recruitment issues	02/03/2010		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes