ISRCTN03813200 https://doi.org/10.1186/ISRCTN03813200

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

Registration date
06/12/2007

Overall study status
Stopped

Last Edited
01/05/2012

Condition category
Skin and Connective Tissue Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data
[_] Record updated in last year

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

Study website
http://www.patchtrial.co.uk

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Multi-centre double-blind randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Prevention

Participant information sheet
For both PATCH I and PATCH II: Full version: http://ctsu.nottingham.ac.uk/ts0601/docs/Participant%20Information%20Sheet%20v1%203.doc Short version: http://ctsu.nottingham.ac.uk/ts0601/docs/Short%20Participant%20information%20sheet%20v1%200.doc Information can also be found at: www.patchtrial.co.uk

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

Secondary outcome measures
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.

Overall study start date
01/01/2007

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

Age group
Adult

Sex
Both

Target number of participants
400

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
England

Ireland

United Kingdom

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

Sponsor information

Organisation
University of Nottingham (UK)

Sponsor details
Research Innovation Services
King's Meadow Campus
University of Nottingham
Lenton lane
Nottingham
England
United Kingdom
NG7 2NR

Sponsor type
University/education

ROR
https://ror.org/01ee9ar58

Funder(s)

Funder type
Charity

Funder Name
The BUPA Foundation (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?
Other publications	discussion of recruitment issues	02/03/2010		Yes	No
Results article	results	01/01/2012		Yes	No