

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	<input type="checkbox"/> Prospectively registered
Registration date 06/12/2007	Overall study status Stopped	<input type="checkbox"/> Protocol
Last Edited 01/05/2012	Condition category Skin and Connective Tissue Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

Prof Hywel Williams

Contact details

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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 prophylactic 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

