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Prophylactic Antibiotics for the Treatment of Cellulitis at Home I

Submission date	Recruitment status	[X] Prospectively registered
21/11/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
04/05/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
03/05/2013	Skin and Connective Tissue Diseases	

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

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Additional identifiers

EudraCT/CTIS number
2006-000381-36

IRAS number

ClinicalTrials.gov number

NCT00552799

Secondary identifying numbers
SP4063

Study information

Scientific Title
A randomised controlled trial of prophylactic antibiotics for the prevention of recurrent cellulitis (erysipelas) of the leg (PATCH I)

Acronym
PATCH I

Study objectives
To ascertain whether antibiotic prophylaxis (penicillin V) can prevent recurrent cellulitis of the leg.

A pilot/feasibility study was performed prior to this trial, and the results published in 2007: http://www.ncbi.nlm.nih.gov/pubmed/17257411.

Please note that as of 23/09/10, this record has been updated. The end date for this study has been extended from 30/06/09 to 31/10/11.

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)
Hospital

Study type(s)
Prevention

Participant information sheet
Can be found on www.patchtrial.co.uk

Health condition(s) or problem(s) studied
Recurrent cellulitis of the leg

Interventions
The anticipated end date of this trial has been amended from 30/06/2007 to 30/06/2009 as of 15 /11/2007. This is due to the incorrect date provided at time of registration and does not reflect a change in the initial trial schedule.

Active group: penicillin V 250 mg twice a day (bd) for 12 months
Inactive group: placebo bd for 12 months

Intervention Type
Drug

Phase
Not Specified

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

Primary outcome measure
Time to next episode of cellulites.

Amended 23/09/10
Follow-up duration for primary endpoints 24 months depending on date of recruitment into trial (Duration of follow up was expected to be 12-18 months, at the time of registration)

Secondary outcome measures
1. Proportion of participants with repeat episodes of cellulitis
2. Proportion of participants with oedema and/or ulceration
3. Number of days in hospital for the treatment of repeat episodes of cellulitis
4. Number of adverse drug reactions reported in each treatment arm
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]).

The time point for each outcome measure will vary with each individual participant but overall they will all be measures throughout the study period which is up to three years from randomisation.

Overall study start date
01/06/2006

Completion date
31/10/2011

Eligibility

Key inclusion criteria

1. Aged over 16 years - no upper age limit, either sex
2. At least one previous episode of cellulitis of either leg within the three years prior to the current acute index episode of cellulitis.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
260

Key exclusion criteria
Added 09/01/2009:
Any doubt about the certainty of the diagnosis of either the index episode or the previous episode (if applicable), will be grounds for exclusion. Additionally, patients with any of the following will be excluded:
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, as these cases are more likely to be caused by staphylococcal infection. (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. This includes, but is not limited to:
5.1. The treating physician and/or patient feels that prophylactic antibiotics are not in the patient's best interests and therefore entry to this study would be inappropriate
5.2. The treating physician and/or patient feels it would not be ethical or appropriate for the patient to receive placebo and so they are not willing/able to accept randomisation
5.3. Concomitant medication that would mean that long-term penicillin is inappropriate
5.4. Diagnostic uncertainty
5.5. Gastrointestinal disease causing persistent diarrhoea or vomiting severe enough to affect the absorption of the phenoxymethylpenicillin
5.6. Allergic diathesis or severe bronchial asthma severe enough to preclude the use of phenoxymethylpenicillin
5.7. Confounding concurrent disease (e.g. deep vein thrombosis [DVT])
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
01/06/2006

Date of final enrolment
31/10/2011

Locations

Countries of recruitment
England

Ireland

United Kingdom

Study participating centre
Centre of Evidence-Based Dermatology
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Sponsor information

Organisation
University of Nottingham (UK)

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Sponsor type
University/education

Website
http://www.nottingham.ac.uk

ROR
https://ror.org/01ee9ar58

Funder(s)

Funder type

Charity

Funder Name
Action Medical Research (UK)

Alternative Name(s)
actionmedres, action medical research for children, AMR

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

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	02/05/2013		Yes	No