

# Prophylactic Antibiotics for the Treatment of Cellulitis at Home I

<b>Submission date</b> 21/11/2005	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
<b>Registration date</b> 04/05/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 03/05/2013	<b>Condition category</b> Skin and Connective Tissue Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

[http://www.ctu.mrc.ac.uk/research\\_areas/study\\_details.aspx?s=90](http://www.ctu.mrc.ac.uk/research_areas/study_details.aspx?s=90)

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

### ClinicalTrials.gov (NCT)

NCT00552799

### Clinical Trials Information System (CTIS)

2006-000381-36

### Protocol serial number

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

## Study type(s)

Prevention

## 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(s)**

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)

**Key secondary outcome(s)**

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.

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**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**

United Kingdom

England

Ireland

**Study participating centre**

**Centre of Evidence-Based Dermatology**

Nottingham

United Kingdom  
NG7 2NR

## Sponsor information

### Organisation

University of Nottingham (UK)

### ROR

<https://ror.org/01ee9ar58>

## Funder(s)

### Funder type

Charity

### Funder Name

Action Medical Research (UK)

### Alternative Name(s)

action medical research for children, actionmedres, The National Fund for Research into Crippling Diseases, AMR

### Funding Body Type

Private sector organisation

### Funding Body Subtype

Trusts, charities, foundations (both public and private)

### Location

United Kingdom

## Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
	results				

<a href="#">Results article</a>		02/05/2013		Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes