ISRCTN86329346 https://doi.org/10.1186/ISRCTN86329346

# Adjunctive Clindamycin For Cellulitis clinical trial (C4C)

| Submission date | Recruitment status |
|---|---|
| 25/10/2013 | No longer recruiting |
| **Registration date** | **Overall study status** |
| 25/10/2013 | Completed |
| **Last Edited** | **Condition category** |
| 15/05/2018 | Skin and Connective Tissue Diseases |

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

**Plain English summary of protocol**

Background and study aims
Cellulitis is an infection of the skin most often caused by a bacterium called Group A streptococcus. Cellulitis is very common and some people can get it more than once. It can make people feel very ill and cause a lot of skin damage, which can take many weeks to get better. The bacterium produces a variety of poisons or 'toxins' which damage the skin in a similar way to a burn. The normal treatment is with an antibiotic called flucloxacillin, which is effective. Another antibiotic called clindamycin is often used to treat a more serious infection, caused by the same bacterium, called necrotising fasciitis. This antibiotic is also sometimes added to, or used after, flucloxacillin if the cellulitis does not appear to be getting better. Clindamycin is added because some doctors think that it will reduce the amount of toxins released by the bacterium. If less toxin is released then there should be less damage. There is some evidence that adding clindamycin helps the patient. We think that if we add clindamycin to the normal flucloxacillin treatment of cellulitis it might reduce the amount of skin damage. If the amount of skin damage is less then the patient will feel less pain and should recover more quickly. This study should tell us whether adding clindamycin is effective and well tolerated.

Who can participate?
Patients aged 18 or over who have a diagnosis of cellulitis of a single, upper or lower, limb.

What does the study involve?
Patients will be randomly allocated to receive flucloxacillin either with or without clindamycin. We will then see which patients get better more quickly. We will give the patient flucloxacillin as soon as the diagnosis of cellulitis is made, so treatment is not delayed. Clindamycin can sometimes cause diarrhoea so we do not want to give it unless it really does make patients get better quickly.

What are the possible benefits and risks of participating?
Participants will receive appropriate treatment and follow up. There are no extra risks compared with the usual treatments.

Where is the study run from?
Bristol Royal Infirmary and 17 other hospitals in the UK

When is the study starting and how long is it expected to run for?
October 2013 to March 2016

Who is funding the study?
NIHR - Research for Patient Benefit (UK)

Who is the main contact?
Lucy Dixon
Bristol.cellulitis@uhbristol.nhs.uk

### Study website
http://www.bristolcellulitis.org/

# Contact information

### Type(s)
Scientific

### Contact name
Dr Richard Brindle

### Contact details
Bristol Royal Infirmary
Marlborough Street
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-
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# Additional identifiers

### EudraCT/CTIS number
2013-001218-14

### IRAS number

### ClinicalTrials.gov number
NCT01876628

### Secondary identifying numbers
15297

# Study information

### Scientific Title
Adjunctive Clindamycin for Cellulitis: Clinical trial comparing flucloxacillin with or without clindamycin for the treatment of limb cellulitis (C4C Trial)

## Acronym
C4C

## Study objectives
The aim of this study is to see whether the addition of Clindamycin, a protein inhibiting antibiotic, to the standard antibiotic treatment of limb cellulitis, with Flucloxacillin, results in less tissue damage and a more rapid resolution of both systemic and local features, in a cost-effective manner.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
13/SC/0211; First MREC approval date 11/06/2013

## Study design
Randomised interventional treatment trial

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
Hospital

## Study type(s)
Treatment

## Participant information sheet
http://www.bristolcellulitis.org/media/2269570/c4c_patient_information_sheet_v1.4_140904.pdf

## Health condition(s) or problem(s) studied
Topic: Injuries and Emergencies, Skin; Subtopic: Injuries and Emergencies (all Subtopics), Skin (all Subtopics); Disease: Injuries and Emergencies, Dermatology

## Interventions
Oral clindamycin or placebo added to IV or PO flucloxacillin for 48 hours.
Study Entry : Single Randomisation only

## Intervention Type
Drug

## Phase
Phase IV

## Drug/device/biological/vaccine name(s)
Clindamycin

### Primary outcome measure
Improvement of systemic and local features; Timepoint(s): Day 1 and Day 5

### Secondary outcome measures
1. Decrease in pain using a visual analogue score (VAS); Timepoint(s): Day 1, Day 5 and Day 10
2. Quality adjusted life years (QALYs) based on the EQ-5D-5L; Timepoint(s): Day 1 and Day 30
3. Recovery of renal function; Timepoint(s): Day 1, Day 5 and Day 10
4. Resolution of composite inflammatory markers; Timepoint(s): Day 1, Day 5 and Day 10
5. Resolution of systemic features; Timepoint(s): Day 1, Day 5 and Day 10
6. Return to work or normal activities; Timepoint(s): Day 1 and Day 30

### Overall study start date
15/10/2013

### Completion date
31/03/2016

## Eligibility

### Key inclusion criteria
1. Male or female subjects aged 18 or over who have a diagnosis of cellulitis of a single, upper or lower, limb
2. Who are able to understand the study and give consent
3. Who are able to take oral medication

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
UK Sample Size: 450

### Key exclusion criteria
1. Patients with a confirmed history of penicillin, flucloxacillin or clindamycin allergy
2. Patients known to be colonised with MRSA or MRSA isolated from wound within the last year
3. Unable to take oral medication
4. Previous history of Clostridium difficile colitis
5. Clindamycin taken within the last 30 days
6. Clinically unstable
7. Unable to understand the study or give consent
8. Any doubt over the certainty of the diagnosis of cellulitis
9. Patients taking any drug that is incompatible with either flucloxacillin or clindamycin

**Date of first enrolment**
15/10/2013

**Date of final enrolment**
30/09/2015

# Locations

**Countries of recruitment**
England

United Kingdom

**Study participating centre**
**Bristol Royal Infirmary**
Bristol
United Kingdom
BS2 8HW

**Study participating centre**
**The Royal London**
London
United Kingdom
E1 1BB

**Study participating centre**
**Royal Devon & Exeter**
Exeter
United Kingdom
EX2 5DW

**Study participating centre**
**Hull Royal Infirmary**
Hull
United Kingdom
HU3 2JZ

**Study participating centre**
**Yeovil District Hospital**
Yeovil

United Kingdom
BA21 4AT

**Study participating centre**
**Doncaster & Bassetlaw Hospital**
Doncaster
United Kingdom
DN2 5LT

**Study participating centre**
**Basingstoke Hospital**
Basingstoke
United Kingdom
RG24 9NA

**Study participating centre**
**King's College Hospital**
London
United Kingdom
SE5 9RS

**Study participating centre**
**Poole Hospital**
Poole
United Kingdom
BH15 2JB

**Study participating centre**
**Royal Lancaster Infirmary**
Lancaster
United Kingdom
LA1 4RP

**Study participating centre**
**St George's Hospital**
London
United Kingdom
SW17 0QT

**Study participating centre**
**Manchester Hospital**
Manchester
United Kingdom
M13 9WL

**Study participating centre**
**Royal United Hospital Bath**
Bath
United Kingdom
BA1 3NG

**Study participating centre**
**Newham Hospital**
London
United Kingdom
E13 8SL

**Study participating centre**
**Portsmouth Hospital - Queen Alexandra Hospital**
Portsmouth
United Kingdom
PO6 3LY

**Study participating centre**
**Northumbria Hospital - North Tyneside General Hospital**
North Shields
United Kingdom
NE29 8NH

**Study participating centre**
**Basildon Hospital**
Basildon
United Kingdom
SS16 5NL

**Study participating centre**

**Leeds General Hospital**
Leeds
United Kingdom
LS1 3EX

# Sponsor information

**Organisation**
University Hospitals Bristol NHS Foundation Trust (UK)

**Sponsor details**
Research & Development
Upper Maudlin Street
Bristol
England
United Kingdom
BS2 8AE

**Sponsor type**
Hospital/treatment centre

**Website**
http://www.uhbristol.nhs.uk/

**ROR**
https://ror.org/04nm1cv11

# Funder(s)

**Funder type**
Government

**Funder Name**
Research for Patient Benefit Programme; Grant Codes: PB-PG-0212-27015

**Alternative Name(s)**
NIHR Research for Patient Benefit Programme, RfPB

**Funding Body Type**
Government organisation

**Funding Body Subtype**
National government

### Location
United Kingdom

# Results and Publications

### Publication and dissemination plan
1. Molecular studies as soon as possible
2. Results February 2016 BMJ
3. Health economics not known
4. Procalcitonin and inflammatory markers not known

### Intention to publish date
01/02/2016

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary
Other

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 17/03/2017 | | Yes | No |
| HRA research summary | | | 28/06/2023 | No | No |