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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

Contact information

Type(s)
Scientific

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Dr Richard Brindle

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Additional identifiers

Clinical Trials Information System (CTIS)
2013-001218-14

ClinicalTrials.gov (NCT)
NCT01876628

Protocol serial number
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

Study type(s)
Treatment

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(s)
Improvement of systemic and local features; Timepoint(s): Day 1 and Day 5

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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
United Kingdom

England

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)

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, Research for Patient Benefit (RfPB), The NIHR Research for Patient Benefit (RfPB), RfPB

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes