

Adjunctive Clindamycin For Cellulitis clinical trial (C4C)

Submission date 25/10/2013	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 25/10/2013	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 15/05/2018	Condition category 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

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

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Bristol Royal Infirmary
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Bristol
United Kingdom
BS2 8HW
-
richard.brindle@uhbristol.nhs.uk

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 hypothesis

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

Condition

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

Overall study end date

31/03/2016

Eligibility

Participant 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

Participant 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

Recruitment start date

15/10/2013

Recruitment end date

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