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Dexamethasone versus placebo for patients with cellulitis

Submission date
20/08/2024

Recruitment status
No longer recruiting

Registration date
11/10/2024

Overall study status
Ongoing

Last Edited
12/05/2026

Condition category
Skin and Connective Tissue Diseases

[X] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Cellulitis is a common bacterial skin infection. Over 300,000 people attend emergency departments in the UK each year with cellulitis. Antibiotic treatment is always recommended to kill the bacteria causing infection but does not always improve symptoms. Symptoms often get worse after starting antibiotics, with pain and swelling increasing in the first few days. Around one-fifth of people see a doctor again for further treatment. There is no evidence that giving out more antibiotics improves symptoms and using excess antibiotics will reduce their effectiveness for everyone (antibiotic resistance). Corticosteroid ("steroid") tablets have been tried as an add-on treatment in a few small studies to reduce swelling, redness and pain. Results have been promising but the studies have been small and more research is needed to find out if steroid tablets work in cellulitis before advising clinicians to routinely use them.
This is a large study to see if prescribing steroid tablets alongside antibiotics improves symptoms and reduces the need for further antibiotics and healthcare visits for patients with cellulitis.

Who can participate?
Patients aged 16 years old or over who come to an NHS emergency or urgent care department with cellulitis.

What does the study involve?
After consent, participants will be put into one of two groups at random. One group will receive steroid (dexamethasone) capsules to take for 2 days, the other group will receive placebo capsules. Both groups will also get the normal treatment for cellulitis (antibiotics and painkillers). Neither the participants nor the clinicians will know which group they are in. The researchers will ask participants about their pain twice a day for three days via electronic survey /text message or telephone call if preferred. They will telephone participants after 14 days to ask about lingering pain, antibiotic and painkiller use and any other healthcare use and after 90 days to see if they have had cellulitis again.

What are the possible benefits and risks of participating?
Dexamethasone is not usually used to treat patients with cellulitis. It is currently unknown whether taking dexamethasone on top of the usual treatments will help symptoms. The main

benefit of taking part is to help us see whether this new treatment works and potentially improve care for patients in the future.

Dexamethasone is widely used for several illnesses, but like all medicines, it does have some possible side effects. This study uses low doses of dexamethasone for a short period, compared to the doses used for some other conditions. Dexamethasone is expected to be active shortly after taking it and wash out of the participant's systems within a few days. Any side effects are also expected to last for a short period. Whilst the risk of side effects with short-term use appears low from previous studies, some of our participants may be at increased risk (e.g. diabetic patients, older patients and those taking non-steroidal anti-inflammatory drugs). A full assessment of these risks is outlined in the trial protocol (section 2.4.0.) and the site teams will be trained in assessing these risks during recruitment.

The PIS outlines the key side effects for participants. As part of the consent conversation, the site team will discuss possible side effects with the participant and answer any questions. There will be a particular focus on diabetic patients, pregnancy and breastfeeding.

Where is the study run from?
University of Exeter (UK)

When is the study starting and how long is it expected to run for?
January 2024 to December 2026

Who is funding the study?
National Institute for Health and Care Research (UK)

Who is the main contact?
DEXACELL@exeter.ac.uk

Contact information

Type(s)
Public, Scientific

Contact name
Dr Study Team

Contact details
Exeter Clinical Trials Unit, University of Exeter
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United Kingdom
EX1 2LU
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Type(s)
Principal investigator

Contact name
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Additional identifiers

Integrated Research Application System (IRAS)
1009877

Central Portfolio Management System (CPMS)
62226

Protocol serial number
5411

Study information

Scientific Title
Dexamethasone as an adjunctive therapy for the management of cellulitis (DEXACELL) - a randomised controlled trial in urgent secondary care

Acronym
DEXACELL

Study objectives
Primary objective:
To establish if the addition of dexamethasone to treat patients with cellulitis reduces total pain reported over the first 3 days compared to a control (placebo).

Secondary objectives:
To determine whether the addition of dexamethasone to treat patients with cellulitis when compared to a control (placebo):
1. Improves quality of life and other patient-reported outcomes
2. Reduces subsequent antimicrobial prescribing, analgesia usage and healthcare utilisation
3. Is cost-effective

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 09/10/2024, South Central – Oxford B Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8134, (0)207 104 8019; oxfordb.rec@hra.nhs.uk), ref: 24/SC/0289

Primary study design

Interventional

Study design
Randomized double-blind parallel-group placebo-controlled trial

Study type(s)
Safety, Other

Health condition(s) or problem(s) studied
Cellulitis at any body site (excluding orbital or periorbital cellulitis)

Interventions
Participants will be randomised into the trial by a delegated member of the site team using an online randomisation service. In addition to usual care, trial participants will be randomised on a 1:1 ratio to receive either:
• Dexamethasone 8mg orally on recruitment, then dexamethasone 8mg orally ~24 hours later.
OR
• Matched placebo capsules on recruitment, then matched placebo capsules ~24 hours later.
For blinding purposes, the active drug will be over-encapsulated. The participant will take two capsules per dose each capsule containing 1 x 4mg tablet of dexamethasone and backfill. Placebo capsules will be manufactured to match in appearance and will not contain any active ingredients. The capsules used may include bovine gelatin and are HALAL-certified. The active tablets have the following excipients; maize starch, microcrystalline cellulose, lactose monohydrate, highly dispersed silicon dioxide, and magnesium stearate. All capsules will contain a backfill made of one of these excipients.

Intervention Type
Drug

Phase
Phase III

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

Primary outcome(s)
Pain measured using a numerical rating scale (NRS; 0-10) at baseline, and then six timepoints post-randomisation at approximately 12-hour intervals

Key secondary outcome(s)
1. Health-related quality of life measured using the EQ-5D-5L at Baseline, Day 3, Day 14 and Day 90 post-randomisation
2. Clinical status measured using the Patient Global Impression of Improvement (PGI-I) daily for the first 3 days and at Day 14 post-randomisation
3. Analgesia usage (number and type of analgesia taken over first 3 days) measured using data obtained via a phone call appointment with the participant on Day 14 post-randomisation
4. Antibiotic usage (route, type, and post-randomisation length of course) up to Day 14 measured using data obtained via a phone call appointment with the participant on Day 14 post-randomisation
5. (Re)admissions to the hospital by Day 14 measured using data obtained via a phone call appointment with the participant on Day 14 post-randomisation

6. Complications of dexamethasone use by Day 14 measured using data obtained via a phone call appointment with the participant on Day 14 post-randomisation
7. Unscheduled healthcare usage until Day 14 measured using data recorded on a bespoke healthcare resource use questionnaire on Day 14 post-randomisation
8. Health, social care and broader societal resource use measured using data recorded on a resource use questionnaire based on the Modular Resource Use core module (ModRUM) tailored to the study population at Baseline and Day 90 post-randomisation
9. Recurrence of cellulitis by Day 90 measured using data obtained via a phone call appointment with the participant at Day 90 post-randomisation
10. Serious and/or potentially related adverse events by day 90 measured using data obtained via a phone call appointment with the participant on Day 14 and Day 90 post-randomisation
11. Pain experienced on Day 14 measured using a numerical rating scale (NRS; 0-10) at Day 14 post-randomisation

Completion date
31/12/2026

Eligibility

Key inclusion criteria
Current inclusion criteria as of 28/11/2024:
1. Aged 16 years old or over
2. A current clinical diagnosis of cellulitis at any body site except the orbit (periorbital/orbital cellulitis)
3. Able to provide informed consent
4. People of child-bearing potential must be willing to:
4.1. Use a highly effective method of contraception (and must agree to continue 3 months after the last dose of the IMP)
4.2. Inform the trial team if pregnancy occurs during trial participation

Previous inclusion criteria:
1. Aged 16 years old or over
2. A current clinical diagnosis of cellulitis at any body site except the orbit (periorbital/orbital cellulitis)
3. Able to provide informed consent
4. People of child-bearing potential must be willing to:
4.1. Use an effective method of contraception (and must agree to continue 3 months after the last dose of the IMP)
4.2. Inform the trial team if pregnancy occurs during trial participation

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
16 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
450

Key exclusion criteria
1. Orbital or periorbital cellulitis, surgical site infection, or planned surgical management (e.g abscess) as managed under a different clinical pathway
2. Allergy to dexamethasone
3. Contraindication to dexamethasone due to concurrent medication (e.g. cobicistat)
4. Has known current invasive fungal infection
5. Has known current gastric or duodenal ulceration
6. Already on corticosteroids - Updated 28/01/2025: Already on systemic corticosteroids
7. Unable to take oral medication
8. Lack of capacity
9. Inability to complete follow-up procedures
10. Prisoner

People of child-bearing potential only:
1. Pregnant, breastfeeding, or planning to conceive in next 3 months

Date of first enrolment
28/02/2025

Date of final enrolment
10/11/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Southmead Hospital
Southmead Road
Westbury-on-trym
Bristol
England
BS10 5NB

Study participating centre
St Georges Hospital
Blackshaw Road
London
England
SW17 0QT

Study participating centre
Addenbrookes Hospital
Hills Road
Cambridge
England
CB2 0QQ

Study participating centre
Bristol Royal Infirmary
Marlborough Street
Bristol
England
BS2 8HW

Study participating centre
Derriford Hospital
Derriford Road
Plymouth
England
PL6 8DH

Study participating centre
Salford Royal Hospital
Stott Lane
Eccles
Salford
England
M6 8HD

Study participating centre
The Royal London Hospital
Alexandra House

London
England
E1 1BB

Study participating centre
Newham General Hospital
Glen Road
London
England
E13 8SL

Study participating centre
Royal Berkshire Hospital
London Road
Reading
England
RG1 5AN

Study participating centre
Hull Royal Infirmary
Anlaby Road
Hull
England
HU3 2JZ

Study participating centre
Manchester Royal Infirmary
Oxford Road
Manchester
England
M13 9WL

Study participating centre
St Marys Hospital
The Bays
South Wharf Road
London
England
W2 1BL

Study participating centre
Leicester Royal Infirmary
Infirmary Square
Leicester
England
LE1 5WW

Study participating centre
John Radcliffe Hospital
Headley Way
Headington
Oxford
England
OX3 9DU

Study participating centre
Wexham Park Hospital
Wexham Street
Wexham
Slough
England
SL2 4HL

Study participating centre
The James Cook University Hospital
Marton Road
Middlesbrough
England
TS4 3BW

Study participating centre
University Hospital Lewisham
Lewisham High Street
London
England
SE13 6LH

Study participating centre
Northern General Hospital
Herries Road

Sheffield
England
S5 7AU

Study participating centre
Watford General Hospital
60 Vicarage Road
Watford
England
WD18 0HB

Study participating centre
Milton Keynes University Hospital
Standing Way
Eaglestone
Milton Keynes
England
MK6 5LD

Study participating centre
Kings College Hospital
Mapother House
De Crespigny Park
Denmark Hill
London
England
SE5 8AB

Sponsor information

Organisation
North Bristol NHS Trust

ROR
https://ror.org/036x6gt55

Funder(s)

Funder type

Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publicly available repository.
Repository name/weblink: University of Exeter Open Research Environment - ORE Home.
The type of data that will be shared: Anonymised research data.
When the data will become available and for how long: After the end of the trial 31/12/2025. Available indefinitely.
For what types of analyses: Not specified.
By what mechanism: Via the University of Exeter Open Research Environment request form. Requests will be reviewed by the Sponsor organisation (North Bristol NHS Trust) before releasing the data.
Whether consent from participants was obtained: Consent is being obtained from participants to share data anonymously to support other research in future.
Comments on data anonymisation: Data will be shared in an anonymised format.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet		11/11/2025	11/11/2025	No	Yes
Protocol file	version 4.0	20/11/2024	28/11/2024	No	No
Protocol file	version 5.0	07/01/2025	28/01/2025	No	No
Statistical Analysis Plan	version 1.0	22/01/2026	17/02/2026	No	No
Statistical Analysis Plan	version 2.0		12/05/2026	No	No

Study website	11/11/2025	11/11/2025	No	Yes