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Oral corticosteroids and colchicine for the treatment of gout flares (OCCUR)

Submission date
29/05/2025

Recruitment status
Not yet recruiting

Registration date
22/07/2025

Overall study status
Ongoing

Last Edited
22/07/2025

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Gout affects 1 in 40 people in the United Kingdom. It causes flares of severe joint pain and swelling and has a big impact on quality of life. Gout flares are very painful and require urgent drug treatment. They are most often treated with anti-inflammatory painkillers such as ibuprofen (sometimes called nonsteroidal anti-inflammatory drugs or NSAIDs). Many people with gout have other medical problems and can't take NSAIDs. For them, gout flares can be treated with colchicine or steroid tablets. We don’t know whether colchicine or steroid tablets work best for treating gout flares in people who cannot take NSAIDs, and which of these causes fewer side-effects.
Aim: To carry out a clinical trial to find out whether colchicine or steroid tablets provide better pain relief from gout flares in people unable to take NSAIDs, which of these causes fewer side-effects, and which is better value for money for the NHS.

Who can participate?
We will complete a trial with 280 adults having a gout flare and who are unable to take NSAIDs.

What does the study involve?
Participants will be recruited from approximately 100 general practices in inner city and rural locations. They will be allocated by chance (randomised) to receive either colchicine or steroid tablets. Participants in both groups will have access to their usual healthcare and will be given a leaflet about gout flares, including information about self-care, rest and ice. Which treatment works best will be assessed by comparing pain between the two groups of participants. We will also ask about how quickly the flare gets better, function, quality of life, side-effects, and cost. All participants will be asked to complete questionnaires at the beginning of the trial and then weekly for 4 weeks. Pain will also be measured twice a day for the first 7 days, then weekly along with the secondary outcomes during weeks 2, 3 and 4.

Being involved in the trial requires time and commitment from the participant to:
1. Complete a baseline questionnaire either online or over the phone which should take approximately 30 minutes.
2. Complete a 7 day pain diary twice daily from the first day of their gout flare for 7 days. This can be completed online or paper. We estimate that this will involve 5 minutes of the

participants time, each time.
3. Complete questionnaires online or on paper at Week 1, week 2, week 3 which should take approximately 10 - 15 minutes.
4. Complete a further full questionnaire at 4 weeks which should take approximately 30 minutes to complete.

What are the possible benefits and risks of participating?
The treatments within this trial both have a marketing authorisation and are widely used to treat gout flares in clinical practice. The practice GP's will be trained in trial procedures and will use their clinical judgement to assess whether or not the participant is suitable to enter the trial according to the inclusion/exclusion criteria.

All medications can potentially cause side-effects. The most common side effects of Colchicine are diarrhoea, feeling sick or being sick. Participants prescribed a statin who are randomised to colchicine will be advised to omit the statin for the duration of colchicine treatment, as per usual NHS care and as advised in our CONTACT trial , which we consider will not impact significantly on long-term cardiovascular risk status.
The most common side effects of prednisolone include heartburn, indigestion, feeling hyperactive, and disturbed sleep or mood. When taken for a long time, steroid tablets can cause more serious problems such as gaining weight, osteoporosis (thin bones), stomach ulcers (damage to the lining of the stomach), eye problems (cataracts and glaucoma), heart attacks and strokes but the risk of these is thought to be small when only taken for a few days. As per usual NHS care the GP will use their clinical judgement to decide whether to also prescribe a proton pump inhibitor to protect the lining of the stomach.

The GP will be trained to advise the participant on the most common side effects of the medications and the appropriate course of action should they experience any.

Where is the study run from?
Keele University (UK)

When is the study starting and how long is it expected to run for?
January 2025 to April 2028

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

Who is the main contact?
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Contact information

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Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
1011829

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
RG-0367-23

Study information

Scientific Title
A pragmatic randomised trial comparing Oral Corticosteroids and Colchicine for the treatment of goUt flaRes in people with relative contraindications to non-steroidal anti-inflammatory drugs. (OCCUR)

Acronym
OCCUR

Study objectives
Primary objective:
To compare the effectiveness of oral prednisolone and colchicine at reducing pain in adults with a gout flare and relative contraindications to NSAIDs in primary care.

Secondary objective:
To compare the:

- effect of oral prednisolone and colchicine on time to resolution of pain, joint swelling and tenderness; treatment side effects, adherence and satisfaction; physical function; quality of life; participant global assessment of treatment response; flare relapse/recurrence; sleep; use of walking aids; analgesic use; health care utilisation; work/education absence.
- cost-effectiveness of oral prednisolone and colchicine.

Ethics approval required
Ethics approval required

Ethics approval(s)
Not yet submitted, to be confirmed, ref: 25/WM/0121

Study design
Interventional randomized parallel group controlled trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
GP practice

Study type(s)
Safety, Efficacy

Participant information sheet

Health condition(s) or problem(s) studied
Gout Flare

Interventions
Participants will be randomised individually in a 1:1 ratio to oral prednisolone 30mg once daily (six 5mg tablets once daily) for five days or oral colchicine 0.5mg three times daily for four days (twice daily if aged≥70 years or known eGFR 15-29).

Follow-up will be the same for both arms of the trial - twice daily during days 1-7, and at weeks 2, 3 and 4 in the form of questionnaires.

Randomisation will be undertaken by authorised personnel (PI or a delegated person) via the CTU Clinical Data Management System (REDCap). This is a secure web-based data collection system that uses a randomisation module; the randomisation sequence will be computer-generated.

Intervention Type
Drug

Pharmaceutical study type(s)
Therapy

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Prednisolone 5mg Tablets, Colchicine 0.5mg tablets

Primary outcome measure
Change in pain intensity from baseline as measured by worst pain intensity in the last 12 hours (0-10 NRS)

Secondary outcome measures
1. Pain intensity (worst pain intensity in the last 12 hours (0-10 NRS)) is measured using self-report at baseline, days 1-7, week 2, week 3 and week 4
2. Joint swelling is measured using self-report at baseline, days 1-7, week 2, week 3 and week 4
3. Joint tenderness is measured using self-report at baseline, days 1-7, week 2, week 3 and week 4
4. Treatment side-effects are measured using self-report at days 1-7, week 2, week 3 and week 4
5. Treatment adherence is measured using self-report at days 1-7, week 2, week 3 and week 4
6. Treatment satisfaction is measured using self-report at day 7 and week 4
7. Physical function is measured using self-report at baseline, day 7 and week 4
8. Quality of life is measured using self-report at baseline, day 7 and week 4
9. Global assessment of treatment response is measured using self-report at day 7 and week 4
10. Flare relapse or recurrence is measured using self-report and defined as recurrence after 48 hours without a flare, assessed at week 4
11. Sleep is measured using self-report at baseline, days 1-7 and week 4
12. Use of walking aids is measured using self-report at baseline, day 7 and week 4
13. Analgesic use is measured using self-report at baseline, days 1-7, week 2, week 3 and week 4
14. Healthcare utilisation is measured using self-report at week 4
15. Work or education absence is measured using self-report at week 4

Overall study start date
01/01/2025

Completion date
30/04/2028

Eligibility

Key inclusion criteria
1. Aged ≥18 years
2. Current clinician-diagnosed gout flare
3. Fulfils Gaffo flare criteria, a validated definition of a gout flare requiring three out of four of:
3.1. Patient-defined flare (or clinician-defined flare if the patient had not had gout previously)
3.2. Pain score at rest of >3 on a 0–10 numeric rating score (NRS)
3.3. At least one swollen joint
3.4. At least one warm joint
4. Contraindication or caution to NSAIDs, defined as at least one of:
4.1. Age ≥65 years
4.2. Known estimated glomerular filtration rate (eGFR) <60 ml/min/1.73m²
4.3. Prescribed anticoagulants

4.4. Allergy to aspirin or NSAID
4.5. Physician-diagnosed asthma
4.6. Physician-diagnosed peptic ulcer disease
4.7. Physician-diagnosed hypertension
4.8. Physician-diagnosed cardiovascular disease
4.9. Physician-diagnosed heart failure
4.10. Physician-diagnosed cerebrovascular disease

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
280

Key exclusion criteria
1. Known eGFR <15 ml/min/1.73m² or undergoing dialysis
2. Solid organ transplant recipients
3. Poorly controlled diabetes mellitus, defined as glycated haemoglobin (IFCC HbA1c) >64 mmol /mol
4. Current active infection
5. Known blood dyscrasias
6. Severe hepatic impairment
7. Previous intolerance of or hypersensitivity to prednisolone or colchicine (or excipients)
8. Taken prednisolone or colchicine for a gout flare in the previous 72 hours
9. Currently prescribed prednisolone for another indication
10. Currently prescribed verapamil, diltiazem, macrolides, HIV protease inhibitors, azole anti-fungals or ciclosporin
11. Known galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption
12. Pregnancy or breastfeeding
13. Women of childbearing potential unless using effective contraceptive measures*
14. Unable or unwilling to provide informed consent
15. Has been randomised in the trial for a previous flare
16. Currently taking part in another gout CTIMP

*Contraceptive methods that can achieve a failure rate of less than 1% per year when used consistently and correctly are considered as highly effective birth control methods.

Date of first enrolment
01/10/2025

Date of final enrolment
01/10/2027

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
-
United Kingdom
-

Sponsor information

Organisation
Keele University

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Sponsor type
University/education

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ROR
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Funder(s)

Funder type
Government

Funder Name

National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Peer reviewed scientific journals
Internal report
Conference presentation
Publication on website
Submission to regulatory authorities
Results of this trial will be reported to the funder (NIHR). The main findings from the trial will be shared with the participating NHS sites and participants via the trial website. The results of this trial will also be shared at relevant conferences and through publication in academic journals which are read by a large number of health professionals. Participants will not be identified individually in any poster, report or publication.

Intention to publish date
30/04/2029

Individual participant data (IPD) sharing plan
Any subsequent requests for access to the anonymised data from anyone outside of the trial team (e.g. collaboration, joint publication, data sharing requests from publishers) will follow Keele CTU's Standard Operating Procedure for data requests.

IPD sharing plan summary
Available on request