

Colchicine or naproxen treatment for acute gout

Submission date 21/11/2013	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 21/11/2013	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 04/11/2019	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Gout is the most common cause of inflamed joints, affecting 1.4% of adults in the UK. Most patients are treated entirely in general practice yet it is frequently not enough. Acute attacks of gout are excruciatingly painful and require urgent drug treatment to reduce inflammation, most commonly with non-steroidal anti-inflammatory drugs (NSAIDs) or colchicine. In GP surgeries, NSAIDs are most commonly used but can cause serious side effects such as stomach ulcers and heart disease, particularly in the elderly. Patients frequently require repeat prescriptions for recurrent attacks of acute gout, increasing the risk of drug-related side-effects. Low-dose colchicine is popular amongst rheumatologists as it is effective and well-tolerated. However, general practitioners (GPs) seldom prescribe colchicine, probably because in the past the recommendation was for high doses to be prescribed, which commonly caused severe diarrhoea. Recently, prescribing recommendations for colchicine have changed, advocating a lower-dose regime. Currently there is no evidence regarding whether NSAIDs or low-dose colchicine is the best treatment for acute gout. This study is the first direct comparison of the effectiveness and side-effects of a NSAID (naproxen) and low-dose colchicine to treat acute gout in GP surgeries.

Who can participate?

Patients aged 18 and over consulting their GP, in participating GP practices, with an acute attack of gout

What does the study involve?

Participants are randomly allocated to receive either low-dose colchicine or Naproxen. Treatment success is assessed by comparing pain reduction between the two drugs using follow-up questionnaires. The study also monitors side-effects, quality of life and cost effectiveness.

What are the possible benefits and risks of participating?

Although there is no expected direct benefit for the patient, it is hoped that the study will improve the understanding of how to treat patients with gout in the future. The study is considered to pose no additional risks to participants than normal care for gout.

Where is the study run from?

The study is run from up to 100 general practices across England.

When is the study starting and how long is it expected to run for?

January 2014 to March 2016

Who is funding the study?

National Institute for Health Research (NIHR) School for Primary Care Research (UK)

Who is the main contact?

Ms Jacqueline Gray

j.gray@keele.ac.uk

Study website

https://www.southampton.ac.uk/medicine/academic_units/projects/contact.page

Contact information

Type(s)

Scientific

Contact name

Ms Jacqueline Gray

Contact details

Arthritis Research UK Primary Care Centre

Primary Care Sciences

Keele University

Newcastle-Under-Lyme

United Kingdom

ST5 5BG

-

j.gray@keele.ac.uk

Type(s)

Scientific

Contact name

Dr Clark Crawford

Contact details

Keele University

Keele

United Kingdom

ST5 5BG

-

research.governance@keele.ac.uk

Additional identifiers

EudraCT/CTIS number

2013-001354-95

IRAS number**ClinicalTrials.gov number**

NCT01994226

Secondary identifying numbers

15555

Study information

Scientific Title

Colchicine Or Naproxen Treatment for ACute gout: a randomised controlled trial

Acronym

CONTACT

Study objectives

A randomised, multi-centre, open-label, active-comparator, pragmatic clinical trial of low-dose colchicine versus naproxen in patients with acute gout.

Ethics approval required

Old ethics approval format

Ethics approval(s)

NRES Committee North West - Haydock, 13/06/2013, ref: 13/NW/0353

Study design

Randomised; Interventional; Design type: Treatment

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

GP practice

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Topic: Primary Care Research Network for England; Subtopic: Not Assigned; Disease: All Diseases

Interventions

Participants will be randomised on a 1:1 basis to low-dose colchicine (500 mcg orally every eight hours for four days) or Naproxen (Single initial dose of 750 mg followed by 250 mg orally every eight hours for up to seven days). Participants will be followed up for 4 weeks.

Intervention Type

Drug

Phase

Phase IV

Drug/device/biological/vaccine name(s)

Colchicine, Naproxen

Primary outcome measure

Pain intensity, measured on a 0-10 pain intensity numeric rating scale over days 0-7

Secondary outcome measures

1. Adherence to trial treatment, measured using patient self report; Timepoint(s): days 1-7
2. Quality of life, measured using EQ-5D 5-L; Timepoint(s): day 7 and 4 weeks
3. Healthcare utilisation (re-attendance at GP/accident and emergency/primary care out-of-hours service), measured using patient self report; Timepoint(s): 4 weeks
4. Patient global assessment of response to treatment, measured using patient self report; Timepoint(s): day 7 and 4 weeks
5. Relapse/recurrence of acute gout, measured using patient self report; Timepoint(s): 4 weeks
6. Side-effects (e.g. nausea, vomiting, dyspepsia, diarrhoea and abdominal pain), measured using a self-reported questionnaire; Timepoint(s): days 1-7, 4 weeks
7. Time off work/education, measured using patient self report; Timepoint(s): 4 weeks
8. Use of other medications for pain relief (e.g. steroids, paracetamol, opiates), measured using patient self report; Timepoint(s): days 1 - 7 and 4 weeks

Overall study start date

25/11/2013

Completion date

31/03/2016

Eligibility

Key inclusion criteria

1. Adults aged 18 years and over
 2. Current attack of acute gout (first attack or recurrent)
 3. Capacity and willingness to give consent and complete the trial paperwork
- Target Gender: Male & Female; Lower Age Limit 18 years

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Planned Sample Size: 400; UK Sample Size: 400

Total final enrolment

399

Key exclusion criteria

1. Known unstable medical conditions (such as ischaemic heart disease, impaired liver function)
2. Known stage 4/5 kidney disease
3. Recent surgery or gastrointestinal bleed
4. History of gastric ulcer
5. Current anticoagulant use
6. Allergy to aspirin/nonsteroidal anti-inflammatory drugs (NSAID)
7. Previous inability to tolerate naproxen or low-dose colchicine
8. Other contraindication to either study drug in accordance with the Summary of Product Characteristics (SPC)
9. Prescription of naproxen or colchicine in the previous 24 hours
10. Pregnant or lactating females
11. Potentially vulnerable
12. Previous participation in the CONTACT trial during a previous acute attack of gout
13. Involvement in another clinical trial of an investigational medicinal product in the last 90 days or any other research within the last 30 days

Date of first enrolment

29/01/2014

Date of final enrolment

31/12/2015

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

Keele University

Newcastle-Under-Lyme

United Kingdom

ST5 5BG

Study participating centre

100 GP sites

United Kingdom

-

Sponsor information

Organisation

University of Keele (UK)

Sponsor details

Keele

Newcastle

England

United Kingdom

ST5 5BG

Sponsor type

University/education

ROR

<https://ror.org/00340yn33>

Funder(s)

Funder type

Government

Funder Name

National Institute for Health Research - School for Primary Care Research (UK)

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

Abstracts have been accepted for oral presentation at the NIHR School for Primary Care Research Showcase November 2016 and British Society for Rheumatology annual conference April 2017. A single paper is planned reporting both the clinical and cost effectiveness outcomes in a high impact journal.

Intention to publish date

01/12/2017

Individual participant data (IPD) sharing plan

The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results	results	28/04/2017	05/05/2017	No	No
Basic results			09/08/2019	No	No
Basic results			09/08/2019	No	No
Results article		01/02/2020	04/11/2019	Yes	No
HRA research summary			28/06/2023	No	No