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Colchicine or naproxen treatment for acute gout

Submission date
21/11/2013

Recruitment status
No longer recruiting

Registration date
21/11/2013

Overall study status
Completed

Last Edited
04/11/2019

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
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Study website
https://www.southampton.ac.uk/medicine/academic_units/projects/contact.page

Contact information

Type(s)
Scientific

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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
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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		28/04/2017	05/05/2017	No	No
Basic results			09/08/2019	No	No
Basic results			09/08/2019	No	No
Results article	results	01/02/2020	04/11/2019	Yes	No
HRA research summary			28/06/2023	No	No