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A short course of low dose steroid tablets as a treatment for painful hand osteoarthritis- does it work?

Submission date	Recruitment status	[ ] Prospectively registered
18/11/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
09/05/2011	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
10/09/2012	Musculoskeletal Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

RR09/8877

Study information

Scientific Title
Treating painful hand osteoarthritis using low dose oral prednisolone: assessing short-term pain and imaging outcomes in a randomised, placebo-controlled, double-blind, 12 week, single centre study

Acronym
POLO

Study objectives
Current treatments for osteoarthritis (OA) have major limitations and other analgesic treatments are needed. Synovitis is prevalent in OA and previous studies have shown it to be a source of pain. Corticosteroids are used in routine practice at treating synovitis in both the inflammatory arthritides and in osteoarthritis and have been shown to be effective at reducing pain.

We propose that treating patients with moderate to severe OA hand symptoms with low dose oral prednisolone will be a practical and safe treatment to reduce synovitis and therefore reduce pain. This will potentially introduce a new treatment into the OA armamentarium which could be of particular use in the primary care setting.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Leeds (West) Research Ethics Committee approved on the 22nd May 2009 (ref: 09/H1307/53)

Study design
Randomised placebo-controlled double-blind single centre study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please contact c.y.j.wenham@leeds.ac.uk to request a patient information sheet

Health condition(s) or problem(s) studied

Painful hand osteoarthritis

Interventions
Patients will be randomised to either one of the following regimens:
1. One capsule containing 5 miligrams of prednisolone daily for 28 days orally
2. Placebo capsule one daily for 28 days orally

The total trial duration will be 12 weeks; 4 weeks of treatment then a follow-up visit 8 weeks later.

Intervention Type
Drug

Phase
Phase IV

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

Primary outcome measure
Change in hand pain VAS, measured from 0 mm (no pain) to 100 mm (severe pain) from baseline to 4 weeks

Secondary outcome measures
1. Change in functional scores (including the Australian/Canadian Osteoarthritis Hand Index [AUSCAN] functional subscale) at 4 and 12 weeks. Measured using the VAS AUSCAN 0 - 100 mm whereby 0 mm = no difficulty and 100 mm = extreme difficulty
2. Change in pain scores (including VAS global disease activity score and AUSCAN pain subscale) at 4 and 12 weeks. Disease activity scores are measured from 0 mm (no activity) to 100 mm (extreme activity). Pain scores are measured from 0 mm (no pain) to 100 mm (extreme pain).
3. Change in Osteoarthritis Quality of Life questionnaire (OAQoL) scores at 12 weeks
4. Change in Hospital Anxiety and Depression Scale (HADS) scores at 4 and 12 weeks
5. Changes on extremity MRI scan at baseline and 4 weeks. MRIs will be scored for synovitis using a semi-quantitative scoring system.

Overall study start date
17/08/2009

Completion date
31/12/2010

Eligibility

Key inclusion criteria
1. Patients must fulfil the American College of Rheumatology criteria for OA of the small joints of the hand
2. Moderately severe symptoms (greater than or equal to 40/100 on hand pain visual analogue scale [VAS] at screening)
3. Symptoms present on most days over the last 3 months
4. A previous radiograph of the hands with changes consistent with osteoarthritis

5. Stable analgesic requirements (including non-steriodal anti-inflammatory drugs [NSAIDs]) for at least 4 weeks
6. Stable doses of chondroitin or glucosamine for 4 months
7. No oral, intramuscular [IM], intra-arterial [IA], or intravenous [IV] steroids during the last 3 months
8. The patient must be able to adhere to the study visit schedule and other protocol requirements
9. The patient must be capable of giving informed consent and the consent must be obtained prior to any screening procedures
10. Aged 43 - 81 years, either sex

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
70

Key exclusion criteria
1. The presence of an inflammatory arthritis
2. Sensitivity, anaphylaxis or allergy to prednisolone
3. Patients who are pregnant, lactating or using hormonal birth control pills
4. Currently uncontrolled diabetes
5. Currently uncontrolled hypertension
6. Current active infection
7. Surgical procedure within 30 days of study initiation
8. Patients with osteoporosis or taking bisphosphonates
9. Patients will not be eligible if they have any contraindications to magnetic resonance imaging (MRI) scanning:
9.1. Pacemakers
9.2. Surgical clips within the head
9.3. Certain inner ear implants
9.4. Neuro-electrical stimulators
9.5. Metal fragments within the eye or head
9.6. Pregnant or breastfeeding women
10. Use of any investigational (unlicensed) drug within 1 month prior to screening or within 5 half-lives of the investigational agent, whichever is longer
11. Subjects with any uncontrolled, unstable or severe medical condition, which in the opinion of the investigator makes them unsuitable for the study

Date of first enrolment
17/08/2009

Date of final enrolment
31/12/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Section of Musculoskeletal Disease
Leeds
United Kingdom
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Sponsor information

Organisation
University of Leeds (UK)

Sponsor details
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Sponsor type
University/education

Website
http://www.leedsth.nhs.uk/

ROR
https://ror.org/024mrxd33

Funder(s)

Funder type
University/education

Funder Name
University of Leeds (UK)

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2012		Yes	No
HRA research summary			28/06/2023	No	No