Hand Osteoarthritis Prednisolone Efficacy study (HOPE)

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22902

Source
Nationaal Trial Register

Brief title
HOPE

Health condition

Hand osteoarthritis
Handartrose

Sponsors and support

Primary sponsor: Leiden University Medical Center, ReumaNederland (Dutch Arthritis Society)
Source(s) of monetary or material Support: ReumaNederland (Dutch Arthritis Society)

Intervention

Outcome measures

Primary outcome

The primary endpoint is the change in digital joint pain after 6 weeks, assessed by a 100 mm VAS.

Secondary outcome

The secondary endpoints are:

- Change in joint pain after 6 weeks assessed by AUSCAN pain subscale;

- Change in thumb base pain after 6 weeks assessed by a 100 mm VAS;

- Change in physical function after 6 weeks assessed by AUSCAN physical function subscale;

- Change in physical function after 6 weeks assessed by FIHOA;

- Change in physical function after 6 weeks assessed by HAQ;

- Change in patient global assessment after 6 weeks assessed by a 100 mm VAS;

- Change in physician global assessment after 6 weeks assessed by a 100 mm VAS;

- Change in number of hand joints with pain upon palpation (physical exam) after 6 weeks;

- Change in inflammatory ultrasonography signs after 6 weeks;

- Change in MRI inflammatory signs after 6 weeks;

- Change in quality of life assessed by SF-36 after 6 weeks;

- Change in grip strength after 6 weeks;

- Fulfilment of OARSI responder criteria(19) after 6 weeks;

- Change in pain, physical function, patient and physician global assessment and quality of life after 8 weeks;

- Change in pain, physical function, patient and physician global assessment, number of painful joints upon palpation, inflammatory signs at US, quality of life, grip strength, and fulfilment of OARSI responder criteria after 14 weeks.

As exploratory parameters we will collect the following questionnaires: fatigue on a 100 mm VAS (baseline, 6 and 14 weeks), Michigan Hand Outcomes Questionnaire (MHOQ) (baseline, 6 and 14 weeks), the Illness Perception Questionnaire (IPQ) (baseline and 14 weeks), the Coping with Rheumatic Stressors questionnaire (CORS) (baseline and 14 weeks), the Hospital Anxiety Depression Scale (HADS) (baseline), the modified painDETECT questionnaire (baseline and 6 weeks) and anchor questions regarding pain, physical function, fatigue and quality of life (after 6 weeks). We will assess hand function using the Moberg Pick Up Test at baseline, 6 and 14 weeks. We will assess hand mobility using different measures, e.g. the Modified Kapandji Index, HAMIS and fingertip-to-palm-distance at baseline, 6 and 14 weeks.

Study description

Background summary

Randomised, placebo-controlled, double-blind, investigator-initiated trial to investigate the efficacy and safety of 6 week prednisolone 10 mg in patients with painful hand OA with signs of inflammation.

Study objective

The main objective of this study will be to identify a possible new treatment to alleviate pain and diminish inflammation in patients with hand osteoarthritis. Secondary objectives are to increase our knowledge on the role of synovial inflammation on symptoms and on the sensitivity-to-change of questionnaires and imaging instruments in hand osteoarthritis.

Study design

Baseline, 2 weeks, 4 weeks, 6 weeks, 8 weeks and 14 weeks.

Intervention

Patients in the intervention group will receive 2 ml prednisolone oral solution once daily (10 mg) during 6 weeks. The control group will receive 2 ml placebo oral solution once daily during 6 weeks. After 6 weeks the medication will be tapered (one week of 1 ml prednisolone oral solution once daily (5 mg) or 1 ml placebo oral solution once daily and thereafter one week 0.5 ml prednisolone oral solution once daily (2.5 mg) or 0.5 ml placebo oral solution once daily).

Contacts

Public
Department of Rheumatology - Leiden University Medical Center
Féline Kroon
PO Box 2300 RC

Leiden
The Netherlands
+31 71 56 3598
Scientific
Department of Rheumatology - Leiden University Medical Center
Féline Kroon
PO Box 2300 RC

Leiden
The Netherlands
+31 71 56 3598

Eligibility criteria

Inclusion criteria

Patients of either sex with “inflammatory” interphalangeal osteoarthritis, defined as at least 4 osteoarthritic
interphalangeal joints (IPJs) with nodes, at least 1 IPJ with soft tissue swelling or erythema and at least 1 IPJ with positive power Doppler signal at US, will be recruited. All patients have to fulfill the American College of
Rheumatology (ACR) criteria for hand osteoarthritis. A minimal amount of osteoarthritic digital pain (pain at rest
>30 mm on VAS) that fluctuates upon drug administration (worsening by >20 mm on the VAS after NSAID wash
out) is required. Patients have to use NSAIDs for digital joint pain. In case of digital pain and thumb base pain,
digital pain has to be the most intense.

Exclusion criteria

Exclusion criteria comprise chronic inflammatory rheumatic disease (such as rheumatoid arthritis or gout),
fibromyalgia, use of immunomodulating drugs (such as antimalarials and systemic or local corticosteroids)
within 90 days, hyaluronic acid injections in the thumb base within 90 days, pregnancy or breastfeeding
during the trial, positive rheumatoid factor or antiCCP
antibodies, psoriasis, blood dyscrasias and coagulation
disorders, malignancy (except successfully treated squamous or basal cell skin carcinoma), uncontrolled
diabetes mellitus or hypertension, unstable ischemic heart disease, heart failure (New York Heart Association III/
IV), severe pulmonary disease, recent stroke, bone marrow hypoplasia, elevated liver enzyme levels (aspartate transaminase (AST) and/or alanine transaminase (ALT) ≥2 times normal value), creatinine clearance ≤60 ml/min, latex sensitivity, drug or alcohol abuse in the last year, severe and opportunistic infections, chronic infections.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2015
Enrollment:	92
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	24-06-2015
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL5034
NTR-old	NTR5263
Other	201500068733 : EudraCT

Study results

Summary results
https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(19)32489-4/fulltext