Hand Osteoarthritis Prednisolone Efficacy study (HOPE)

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Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22902

Bron
NTR

Verkorte titel
HOPE

Aandoening

Hand osteoarthritis
Handartrose

Ondersteuning

Primaire sponsor: Leiden University Medical Center, ReumaNederland (Dutch Arthritis Society)
Overige ondersteuning: ReumaNederland (Dutch Arthritis Society)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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).

Contactpersonen

Publiek

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

Leiden

The Netherlands
+31 71 56 3598

Wetenschappelijk

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

Leiden
The Netherlands
+31 71 56 3598

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-09-2015
Aantal proefpersonen:	92
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	24-06-2015
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5034
NTR-old	NTR5263
Ander register	201500068733 : EudraCT

Resultaten

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