# Pharmacological Treatment in Hand Osteoarthritis

Published: 15-04-2010
Last updated: 15-05-2024

To evaluate the efficacy of 400 mg QD hydroxychloroquine in hand OA patients after 24 weeks of treatment.

| | |
|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Other condition |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON38184

**Source**
ToetsingOnline

**Brief title**
FABIO

### Condition

- Other condition

**Synonym**
degenerative arthritis, degenerative joint disease

**Health condition**

gewrichtaandoening

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Maasstadziekenhuis
**Source(s) of monetary or material Support:** Maasstad Ziekenhuis

## Intervention

**Keyword:** arthrosis, hand OA, hydroxychloroquine, osteoarthritis

## Outcome measures

### Primary outcome

Pain intensity at week 24 (100 mm VAS) compared to baseline

### Secondary outcome

Hand function at week 24 (AUSCAN and AIMS2-SF) compared to baseline

Pain intensity at week 6 and 12 compared to baseline

Radiographic progression at week 24

# Study description

### Background summary

Osteoarthritis is the most common joint disease, most frequently involving the hands, resulting in pain, stiffness and loss in hand function. At present, there is no way to prevent the onset or the progression of hand osteoarthritis (OA). It is believed that inflammation plays a important role in the pathogenesis of OA and that anti-inflammatory drugs might be an effective treatment for OA. Anti-malarial agents like chloroquine and hydroxychloroquine are potential anti-inflammatory drugs and hydroxychloroquine has already proven to be an effective suppressor of inflammation in rheumatoid arthritis. Several previous studies with hydroxychloroquine in hand OA also showed a possible effect on pain and inflammation, but these studies were mostly retrospective and done with a small number of patients.

### Study objective

To evaluate the efficacy of 400 mg QD hydroxychloroquine in hand OA patients after 24 weeks of treatment.

### Study design

Randomised, double blind, placebo controlled study

### Intervention

Hydroxychloroquine 400 mg or placebo capsule QD for 24 weeks.

### Study burden and risks

2 visits (day 0 and week 24)
2 follow up telephone calls (week 6 and 12)
4 questionnaires (day 0, week 6, 12 and 24)
1 diary
1 radiograph of both hands

## Contacts

**Public**
Maasstadziekenhuis

Maasstadweg 21
Rotterdam 3079DZ
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**Scientific**
Maasstadziekenhuis

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

**Age**
Adults (18-64 years)
Elderly (65 years and older)

## Inclusion criteria

Age * 40 years
Primary hand OA according to the ACR classification
Heberden or Bouchard nodule or Kellgren-Lawrence grade 1, 2 or 3 in * 2 symptomatic joints
Pain in the dominant hand * 12 months
Use of an NSAID for * 1 episode of pain
Written informed consent

## Exclusion criteria

Secondary hand OA, e.g. hemochromatose, rheumatoid arthritis, posttraumatic
Kellgren-Lawrence grade 4 OA
Use of hydroxychloroquine within 3 months before entering the study
Use of NSAIDs or corticosteroids within 7 days before entering the study
Retinopathy
Myastenia Gravis
Known allergy or hypersensitivity for hydroxychloroquine

# Study design

## Design

| | |
|---|---|
| Study phase: | 3 |
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Double blinded (masking used) |
| Control: | Placebo |
| Primary purpose: | Treatment |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 16-09-2010 |
| Enrollment: | 200 |
| Type: | Actual |

### Medical products/devices used

| | |
|---|---|
| Product type: | Medicine |
| Brand name: | Plaquenil |
| Generic name: | hydroxychloroquine |
| Registration: | Yes - NL outside intended use |

## Ethics review

| | |
|---|---|
| Approved WMO Date: | 15-04-2010 |
| Application type: | First submission |
| Review commission: | MEC-U: Medical Research Ethics Committees United (Nieuwegein) |
| Approved WMO Date: | 09-06-2010 |
| Application type: | First submission |
| Review commission: | MEC-U: Medical Research Ethics Committees United (Nieuwegein) |
| Approved WMO Date: | 18-01-2011 |
| Application type: | Amendment |
| Review commission: | MEC-U: Medical Research Ethics Committees United (Nieuwegein) |
| Approved WMO Date: | 03-08-2011 |
| Application type: | Amendment |
| Review commission: | MEC-U: Medical Research Ethics Committees United (Nieuwegein) |
| Approved WMO Date: | 05-09-2011 |
| Application type: | Amendment |
| Review commission: | MEC-U: Medical Research Ethics Committees United (Nieuwegein) |

# Study registrations

## Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 25343
Source: Nationaal Trial Register
Title:

## In other registers

| Register | ID |
|---|---|
| EudraCT | EUCTR2010-019684-11-NL |
| CCMO | NL32030.101.10 |
| OMON | NL-OMON25343 |