

# Hydroxychloroquine (HCQ) in patients with inflammatory osteoarthritis (OA) of the hands

<b>Submission date</b> 10/05/2011	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 09/06/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 19/05/2022	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof Gerd - R. Burmester

**Contact details**  
Charité - University of Medicine, Berlin  
Department of Rheumatology and Clinical Immunology  
Charitéplatz 1  
Berlin  
Germany  
10117

## Additional identifiers

**Clinical Trials Information System (CTIS)**  
2011-001689-16

**Protocol serial number**  
2011 05 30-1

## Study information

**Scientific Title**

Prospective, randomised, double-blind, placebo-controlled clinical trial with hydroxychloroquine (HCQ) in patients with inflammatory osteoarthritis (OA) of the hands

## **Acronym**

OA Treat

## **Study objectives**

Osteoarthritis (OA) is a heterogeneous group of conditions with a disturbed integrity of articular cartilage and changes in the underlying bone. The pathogenesis of OA is multifactorial and involves a complex interplay of genetic, metabolic, biochemical, and biomechanical factors with variable components of inflammation. The disease, as one of the most prevalent musculoskeletal diseases, leads to pain in and around the affected joints and to swelling, stiffness, deformity, and gradual loss of function. It is not just a disease of elderly people, but also affects the younger working age population. Hydroxychloroquine (HCQ) is a disease modifying anti-rheumatic drug (DMARD) that in clinical practice is also used for inflammatory OA and has been employed for the treatment of various rheumatic and dermatologic diseases. Current research has further enhanced our understanding of the pharmacologic mechanisms of action of these drugs involving inhibition of endosomal toll - like receptor (TLR) signalling, which limits B cells and dendritic cell activation. Three studies of HCQ in OA, including one abstract and one letter are available. Most studies show that currently a wide variety of outcome measures are used in rather small patient populations.

Despite initial indications for a good effect of HCQ, there has been no randomized, double-blind, and placebo-controlled trial in a larger patient group. In the European League Against Rheumatism (EULAR) evidence based recommendations for the management of hand OA HCQ was not included as a therapeutic option, apparently because of the currently missing randomized clinical trials. The aim of the proposed study is to investigate the efficacy of HCQ by clinical and radiological outcome compared to placebo in patients with severe and refractory inflammatory hand OA.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Approved as of 17/04/2013

## **Primary study design**

Interventional

## **Study design**

Interventional randomised placebo-controlled double-blind multicentre study

## **Study type(s)**

Treatment

## **Health condition(s) or problem(s) studied**

Refractory inflammatory hand osteoarthritis

## **Interventions**

#### Arm 1:

1. Capsules body weight adapted to pharmaceutical package (30 - 49 kg one capsule with 200 mg HCQ as daily single dose
2. 50 - 64 kg one capsule with 200 mg HCQ as single dose on day 1 and two capsules with 200 mg HCQ as single dose on day 2
3. > 65 kg two capsules with 200 mg HCQ as single dose

#### Arm 2:

One capsule with oral placebo application characteristics

### **Intervention Type**

Drug

### **Phase**

Phase III

### **Drug/device/biological/vaccine name(s)**

Hydroxychloroquine

### **Primary outcome(s)**

1. Australian-Canadian OA Index (AUSCAN, German version) for pain, and hand disability as co-primary clinical outcome at week 52
2. Radiographic co-primary endpoint: Radiographic progression assessed by the Kallman Score at week 52

### **Key secondary outcome(s)**

1. Efficacy of HCQ with respect to AUSCAN at week 26 to patients global assessment of disease activity, patients assessment of stiffness, and physicians global assessment of disease activity at week 26, 52
2. To compare pain, functioning, disability, quality of life, patient-acceptable symptoms and health (HAQ, SF-36, SACRAH, FiHOA, AUSCAN, Backman score, etc.) week 0, 26, 52
3. To assess and to compare the inflammatory status using the following parameters: joint pain and joint swelling, night pain, morning stiffness, local erythema/redness, CRP - and ESR - levels from baseline to week 26, 52
4. To compare cumulative dosage of consumption per week of standard therapy (NSAIDs, COXibs)
5. Assessment of safety: Safety and tolerability of HCQ with reports on adverse event (AE) and serious adverse event (SAE)
6. The eye examination will be performed by an ophthalmologist (baseline and every 6 months)

### **Completion date**

05/07/2018

## **Eligibility**

### **Key inclusion criteria**

1. Men and women from 40 to 80 years
2. Presence of clinical hand OA according to American College of Rheumatology (ACR) criteria
3. Conforming to the ACR criteria for hand OA with recent X ray, dating less than 6 months ago, X ray of the hands showing radiological signs of digital OA in one or more joints as defined by grades 2 or higher, per Kellgren and Lawrence scale or alternatively using the Kallman method

or alternatively using the Verbruggen Score;

4. Symptomatic digital OA with more than three finger joints for more than 3 months (at least every other day) despite taking analgesics and non-steroidal anti-inflammatory drugs (NSAIDs)
5. Pain above 35 mm as evaluated by the Australian/Canadian Osteoarthritis Hand Index (AUSCAN) -Visual Analogue Scale( VAS) (0 - 100 mm)
6. Function as co-primary clinical outcome with  $\geq 9$  using the AUSCAN LK function subscale, or  $\geq 225$  F (out of maximum of 800) on the AUSCAN VA function subscale

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Sex**

All

### **Key exclusion criteria**

1. Patients who have already been treated with HCQ
2. Existence of painful syndrome of upper limbs likely to interfere with the monitoring of pain
3. Patients suffering or having suffered from secondary OA after one of the following diseases (e.g. infectious arthritis, acromegaly, ochronosis, haemochromatosis, gout, etc.) or inflammatory joint diseases
4. Any unstable medical condition which would put the patient at an unacceptable risk
5. Planned Surgery
6. Local injection with glucocorticoids or other medications within the previous three months
7. Oral glucocorticoids
8. Presence of retinopathy

### **Date of first enrolment**

04/12/2011

### **Date of final enrolment**

31/12/2015

## **Locations**

### **Countries of recruitment**

Germany

### **Study participating centre**

Charité - University of Medicine, Berlin

Berlin

Germany

10117

# Sponsor information

## Organisation

Charité - University of Medicine, Berlin (Germany)

## ROR

<https://ror.org/001w7jn25>

# Funder(s)

## Funder type

Government

## Funder Name

German Federal Ministry of Education and Research (Bundesministerium Fur Bildung und Forschung [BMBF]) (Germany)

# Results and Publications

## Individual participant data (IPD) sharing plan

Not provided at time of registration

## IPD sharing plan summary

Not provided at time of registration

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>	protocol	27/10/2014		Yes	No
<a href="#">Basic results</a>		21/03/2022	19/05/2022	No	No