The effects on bone metabolism in patients using hydroxychloroquine

Published: 30-06-2015
Last updated: 21-04-2024

Primary Objective: To evaluate the change in serum βCTX in patients who start with HCQ treatment.Secondary Objective(s): To evaluate the change in serum PINP and BAP in patients who start with HCQ treatment

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bone disorders (excl congenital and fractures)
Study type	Observational invasive

Summary

ID

NL-OMON42271

Source
ToetsingOnline

Brief title
HCQ and bone metabolism

Condition

- Bone disorders (excl congenital and fractures)

Synonym
osteoporosis

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: own funding

Intervention

Keyword: Bone mineral density, Bone turnover markers, hydroxychloroquine

Outcome measures

Primary outcome

The main outcome of this study is to evaluate the changes in beta-CTX due to

HCQ treatment.

Secondary outcome

To evaluate the change in serum PINP and BAP in patients who start with HCQ

treatment

Study description

Background summary

In our previous study we found that patients with pSS have higner bone mass compared to healthy controls.
We performed a biochemical pilot study to evaluate the effects of HCQ on bone metabolism. The preliminary data of this study revealed that HCQ has few effect on bone formation, however, bone resorption was significantly decreased compared to the controls. This effect was monitored after three weeks. The data supports our clinical data from the previous study. However, the duration and dose of HCQ in those patients are not known.

Study objective

Primary Objective:
To evaluate the change in serum βCTX in patients who start with HCQ treatment.

Secondary Objective(s):
To evaluate the change in serum PINP and BAP in patients who start with HCQ treatment

Study design

The current study is designed as an observational study

Patients will be recruited at the outpatient clinic of the Internal Medicine in the Erasmus Medical Centre or at the Department of Rheumatology of both the Maasstad Hospital and Sint Franciscus Gasthuis.

All patients with inflammatory arthritis, pSS, sarcoidosis, RA or SLE and therefore require treatment with HCQ will be invited to participate in the present study. We will not administer HCQ to healthy controls or patients who do not need HCQ for its current condition. In the current study we measure serum BTMs at baseline and three months after treatment. The following BTMs will be measured: PINP, BAP and ßCTX. Also, we will measure all participants vitamin D status.

In addition, we will collect demographical data from all participants such as BMI and smoking history.

We will store blood samples of every participant.

Study burden and risks

In the current study, patients only have to give extra blood. In total, two times 80mL extra blood will be collected. There is no risk involved during the study for patient*s health.

Contacts

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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 > 18 years
Patients with pSS, sarcoidosis, RA or SLE who start with HCQ

Exclusion criteria

Other underlying auto-immune disease
Use of medications against osteoporosis (e.g. bisphosphonates)
Severe vitamin D deficiency (serum level < 20 nmol/L)
Untreated hyperthyroidism
Untreated hyperparathyroidism
Use of corticosteroids (prednisone equivalent of > 7.5 mg for > 3 months in the last year)
Multiple myeloma
Mastocytosis

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped

Start date (anticipated):	01-07-2015
Enrollment:	81
Type:	Actual

Ethics review

Approved WMO Date:	30-06-2015
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
CCMO	NL51938.078.14