ISRCTN79343755 https://doi.org/10.1186/ISRCTN79343755

# Efficacy of methotrexate on chronic calcium pyrophosphate dihydrate deposition disease (chondrocalcinosis)

**Submission date**
11/01/2008

**Recruitment status**
No longer recruiting

**Registration date**
10/03/2008

**Overall study status**
Completed

**Last Edited**
13/09/2017

**Condition category**
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

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

## Contact information

**Type(s)**
Scientific

**Contact name**
Dr Axel Finckh

**Contact details**
Av. Beau Séjour 26
Geneva-14
Switzerland
CH-1211

## Additional identifiers

**Clinical Trials Information System (CTIS)**
2007-003479-37

## Study information

**Scientific Title**
Efficacy of methotrexate on chronic calcium pyrophosphate dihydrate deposition disease (chondrocalcinosis) - a randomised controlled trial

**Study objectives**

Methotrexate is efficient in controlling symptoms and signs of chronic chondrocalcinosis.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Ethics approval received from Swissmedic, the Swiss Agency for Therapeutic Products on the 2nd July 2007 (ref: 2007DR3150; protocol: 06-167)

## Primary study design
Interventional

## Study design
Double-blind crossover randomised controlled trial

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Chronic calcium pyrophosphate dihydrate (CPPD) arthropathy

## Interventions
Patients will be randomised to receive either methotrexate (10 - 15 mg/week intramuscular [im] injections) or placebo during an initial treatment period of three months, followed by a wash-out period of one month, and a subsequent treatment period of three months with the alternative regimen. The total duration of follow-up will be eight months (three months in one arm and two months wash-out and three months in the other arm).

## Intervention Type
Drug

## Phase
Not Specified

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

## Primary outcome(s)
The primary outcome will be arthritic disease activity, measured by the DAS44 (disease activity score on 44 joints), and pain levels, measured by a patient visual analogue scale.

## Key secondary outcome(s)
Secondary outcomes will be:
1. Number of acute arthritis flares
2. Patients global assessment
3. Function of the target joints
4. Erythrocyte sedimentation rates
5. Number of tender and swollen joints
6. Number of analgesic pills
7. Safety and tolerability of methotrexate

### Completion date
31/12/2010

## Eligibility

### Key inclusion criteria
1. Definite chronic calcium pyrophosphate dihydrate (CPPD) deposition disease using the McCarty diagnostic criteria
2. Recurrent mono- or oligo-arthrits ('pseudogout') (at least three flares/six months) or persistent poly-arthritis
3. Unsatisfactory response on at least one non-steroidal anti-inflammatory drug (NSAID) or low dose glucocorticoids (defined by the patient), OR contraindication to NSAIDs and glucocorticoids (defined by the physician)
4. Informed consent
5. Patients 18 years and over, either sex

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 Years

### Sex
All

### Key exclusion criteria
1. Contraindication to methotrexate (MTX):
1.1. Hepatic failure
1.2. Important alcohol consumption
1.3. Severe renal failure
1.4. Haematological disease
1.5. Acute infection
2. Diagnosis of rheumatoid arthritis, connective tissue disease, psoriatic arthritis, gout or any other chronic or recurrent disease associated with oligo- or poly-arthritis
3. Inability to fill out a questionnaire in the local language
4. Pregnancy (negative pregnancy test), lactation, or refusal to use an effective form of contraception for all participants in child-baring age

### Date of first enrolment
01/10/2007

### Date of final enrolment
31/12/2010

# Locations

### Countries of recruitment
Ireland

Switzerland

### Study participating centre
**Av. Beau Séjour 26**
Geneva-14
Switzerland
CH-1211

# Sponsor information

### Organisation
Geneva University Hospitals (Switzerland)

### ROR
https://ror.org/01m1pv723

# Funder(s)

### Funder type
Hospital/treatment centre

### Funder Name
Geneva University Hospitals (Switzerland) - clinical research grant

# Results and Publications

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary
Not provided at time of registration

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| | results | | | | |

| | | | | |
|---|---|---|---|---|
| Results article | exploratory analysis | 15/10/2014 | Yes | No |
| Other publications | | 01/02/2007 | Yes | No |