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

Submission date Recruitment status Prospectively registered 11/01/2008 No longer recruiting [] Protocol [] Statistical analysis plan Registration date Overall study status 10/03/2008 Completed [X] Results [] Individual participant data Last Edited Condition category 13/09/2017 Musculoskeletal Diseases

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

Av. Beau Séjour 26 Geneva-14 Switzerland CH-1211

Additional identifiers

EudraCT/CTIS number 2007-003479-37

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

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)

Study design

Double-blind crossover randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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)

Primary outcome measure

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.

Secondary outcome measures

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

Overall study start date

01/10/2007

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

60

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)

Sponsor details

Rue Micheli du Crest Geneva-14 Switzerland CH-1211

Sponsor type

Hospital/treatment centre

Website

http://www.hug-ge.ch/

ROR

https://ror.org/01m1pv723

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Geneva University Hospitals (Switzerland) - clinical research grant

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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?
Other publications	exploratory analysis	01/02/2007		Yes	No
Results article	results	15/10/2014		Yes	No