

Anakinra in the treatment of acute calcium pyrophosphate arthritis

Submission date 28/02/2011	Recruitment status No longer recruiting	☒ Prospectively registered
		☐ Protocol
Registration date 18/03/2011	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 18/03/2011	Condition category Musculoskeletal Diseases	☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number

14-11

Study information

Scientific Title

A multicentre, randomised, controlled, double-blind study, evaluating the efficacy and safety of anakinra in chondrocalcinosis (Étude multicentrique randomisée contrôlée en double-aveugle contre placebo, évaluant l'efficacité et la sécurité de l'anakinra dans la crise de chondrocalcinose articulaire)

Acronym

APAC

Study objectives

To demonstrate that 3 x daily injections of anakinra is effective in treatment of acute symptoms of calcium pyrophosphate arthritis in comparison with an active comparator, prednisolone 30mg daily for 3 days

Ethics approval required

Old ethics approval format

Ethics approval(s)

Cantonal ethics committee for research on human (Commission cantonale d'éthique de la recherche sur l'être humain"), the date of approval 20/2/2011, reference no: 14/11

Primary study design

Interventional

Study design

Randomised double blind controlled study

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Chondrocalcinosis

Interventions

3 x daily injection of anakinra 100mg versus 3 x daily oral intake of prednisolone 30mg.

The primary end point is at day 7 and the study will run over a total of 28 days.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Anakinra

Primary outcome(s)

Visual Analogue Scale (VAS) pain score of arthritis in the target joint at 72h

Key secondary outcome(s)

1. Effect of therapy on pain and symptoms of arthritis up to day 28 using a VAS and Likert scales for pain and patient and physician assessment of signs and symptoms of inflammation
2. Tolerance and side effects of the treatments will be assessed by the investigators

Completion date

31/12/2011

Eligibility

Key inclusion criteria

1. Informed consent
2. Male or female from 18-99 years of age
3. Diagnosis of acute calcium pyrophosphate arthritis based on symptoms of acute arthritis and presence of crystals of chronic calcium pyrophosphate dihydrate (CPPD) in the synovial liquid at screening or from a prior analysis
4. The start of the acute arthritis should be less than 5 days from inclusion in the study

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Upper age limit

99 Years

Sex

All

Key exclusion criteria

1. Corticotherapy orally with dose equivalent of prednisone > 10mg during the 24 h preceding inclusion
2. Corticotherapy intramuscular (im) or intravenous (iv) during the 72h preceding inclusion, no matter the dose
3. Corticotherapy intra-articularly during 7 days preceding inclusion
4. Chronic oral corticotherapy of > 10mg daily
5. Uncontrolled respiratory or cardiac failure
6. Other causes of acute arthritis
7. Active gastric or duodenal ulceration
8. Untreated and active malignancy
9. Known intolerance or allergy to the study medications
10. Active and untreated infection assessed by investigator as a contraindication to study medications
11. Other medical problems that are judged prejudicial to the inclusion of the patient in the study by the investigator
12. Pregnancy or active breast feeding

Date of first enrolment

01/05/2011

Date of final enrolment

31/12/2011

Locations

Countries of recruitment

Switzerland

Study participating centre**Service de Rhumatologie**

Lausanne

Switzerland

1011

Sponsor information

Organisation

University Hospital Centre and University of Lausanne (CHUV) (Switzerland)-Service of Rheumatology

ROR

<https://ror.org/05a353079>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

University Hospital Centre and University of Lausanne (CHUV) (Switzerland) -Research Fund of the Service of Rheumatology

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Not provided at time of registration