

# Anakinra in the treatment of acute calcium pyrophosphate arthritis

<b>Submission date</b> 28/02/2011	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 18/03/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 18/03/2011	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Dr Alexander So

### 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 lanakinra 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

**Study design**

Randomised double blind controlled study

**Primary study design**

Interventional

**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