ISRCTN46471047 https://doi.org/10.1186/ISRCTN46471047

Anakinra in the treatment of acute calcium pyrophosphate arthritis

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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 lefficacité 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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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

Secondary outcome measures
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

Overall study start date
01/05/2011

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
99 Years

Sex
Both

Target number of participants
75

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. Pregancy 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

Sponsor details
Service de Rhumatologie
c/o Prof Alexander So
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Sponsor type
Hospital/treatment centre

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

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