Pilot study of efficacy of anakinra in acute gouty arthritis

Submission date	Recruitment status	Prospectively registered
21/11/2006	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
04/01/2007	Completed	[X] Results
Last Edited 29/11/2007	Condition category Musculoskeletal Diseases	Individual participant data

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 2006-1

Study information

Scientific Title

Study objectives

Treatment with anakinra will decrease the signs and symptoms of acute gout.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics committee approval is pending, approval expected in January 2007.

Study design

Open label pilot study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Acute gout

Interventions

Treatment with 100 mg anakinra daily subcutaneously for three days

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Anakinra

Primary outcome(s)

- 1. Pain of arthritis
- 2. Signs of arthritis

Key secondary outcome(s))

Biological markers of inflammation

Completion date

31/01/2007

Eligibility

Key inclusion criteria

- 1. Acute gout as defined by American College of Rheumatology (ACR) criteria
- 2. Acute arthritis due to gout which is unresponsive to conventional therapy with Non-Steroidal Anti-Inflammatory Drugs (NSAIDs), colchicine or steroids
- 3. Patients with acute gout who have had side effects or intolerance to either NSAIDs, colchicine or steroids

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

- 1. Patients with on-going or untreated infectious diseases
- 2. Patients with rheumatoid arthritis, lupus or vasculitis
- 3. Patients concurrently treated with anti-Tumour Necrotising Factor (TNF) therapies
- 4. Patients with active cancer

Date of first enrolment

01/12/2006

Date of final enrolment

31/01/2007

Locations

Countries of recruitment

Switzerland

Study participating centre Rheumatology Service

Lausanne Switzerland 1011

Sponsor information

Organisation

University Hospital Complex of Vaud (Centre Hospitalier Universitaire Vaudois [CHUV]) (Switzerland)

ROR

https://ror.org/05a353079

Funder(s)

Funder type

University/education

Funder Name

Service of Rheumatology of the Centre Hospitalier Universitaire, Vaudois (Switzerland)

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 article	Results	01/09/2007		Yes	No