ISRCTN10862635 https://doi.org/10.1186/ISRCTN10862635

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	**Condition category**	[ ] Individual participant data
29/11/2007	Musculoskeletal Diseases	

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
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

Secondary study design
Non randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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 measure
1. Pain of arthritis
2. Signs of arthritis

Secondary outcome measures
Biological markers of inflammation

Overall study start date
01/12/2006

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

Age group
Adult

Sex
Both

Target number of participants
10

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)

Sponsor details
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Sponsor type
University/education

Website
http://www.chuv.ch/

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

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?
Results article	Results	01/09/2007		Yes	No