The effect of IL-1 inhibition by anakinra in acute gout;- A proof of concept study-

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Primary:To evaluate the efficacy and safety of anakinra in the treatment of pain in patients with an acute gout attack during 3 days and subsequently assess the effect of anakinra treatment for 21 days in the prevention of recurrent gout attacks....

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON40227

Source
ToetsingOnline

Brief title
The effect of IL-1 inhibition by anakinra in acute gout

Condition

- Joint disorders

Synonym
Gout.

Research involving
Human

Sponsors and support

Primary sponsor: Jan van Breemen Instituut
Source(s) of monetary or material Support: Reade;centrum voor revalidatie en reumatologie

Intervention

Keyword: Acute gout, Anakinra, IL-1 inhibition

Outcome measures

Primary outcome

The reduction in VAS (Visual Analog Scale) pain after 72 hours of anakinra

treatment.

Secondary outcome

The changes in markers of inflammation and endothelial function, changes in

arterial stiffness and microcirculation after 7 and 21 days of treatment with

anakinra.

Study description

Background summary

Urate crystals stimulate the IL 1 production in monocytes and synovial macrophages by inflammasomes. Recent evidence proposed a relationship between urate and atherosclerosis. Based on this, it is likely that this mechanism plays a role in the increased cardiovascular risk in gout patients. Therefore, it is important to investigate the effect of the IL 1 inhibition by interleukine antagonist anakinra on patients with acute gout. The objectives of this trial are twofold. First, the reduction of pain in patients with acute gout is investigated. Second the cardiovascular risk in gout patients is investigated.

Study objective

Primary:To evaluate the efficacy and safety of anakinra in the treatment of pain in patients with an acute gout attack during 3 days and subsequently assess the effect of anakinra treatment for 21 days in the prevention of recurrent gout attacks.

Secondary: To assess the effect of anakinra on the endothelium and microcirculation of patients with acute gout attack during the study and subsequently evaluate the impact of anakinra on cardiovascular risk, after

respectively 3 and 21 days of treatment.

Study design

Randomized, double-blind, clinical trial in patients with acute gout. All included patients will receive anakinra, 100mg o.d. by subcutaneous injection for 3 consecutive days. The first injection needs to be administred within 24 hours after the acute attack is first reported. After 3 days patients will either continue on anakinra, 100 mg o.d. by subcutaneous injection or switch to placebo for the remaining 18 days of the study.

Intervention

All included patients will receive anakinra, 100 mg o.d. by subcutaneous injection for 3 consecutive days. The first injection needs to be administred within 24 hours after the acute attack is first reported. After 3 days patients will either continue on anakinra, 100 mg o.d. by subcutaneous injection or switch to placebo for the remaining 18 days of the study.

Study burden and risks

Consists of an extra blood sample and additionally measurements of endothelial function.

Contacts

Public
Jan van Breemen Instituut

dr Jan van Breemenstraat 2
Amsterdam 1056 AB
NL
Scientific
Jan van Breemen Instituut

dr Jan van Breemenstraat 2
Amsterdam 1056 AB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients with a crystal-confirmed diagnosis of gout
Patients with known intolerance or contra-indications for colchicine and NSAIDs and relative contra-indications to systemic prednisolone.
Patients with a currently acute gout flare

Exclusion criteria

Patients with latent (or active) tuberculosis,
Positive serology for hepatitis B or C,
Patients with diabetes mellitus,
Patients with an extended history of cardiovascular disease
Patients s with a creatinine clearance less than 30 ml/min
Patients willing to receive an standard treatment conform the ACR guidelines 2012 and who do not agree to participate in the study

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-03-2017
Enrollment:	20
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Anakinra
Generic name:	Kineret
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO

Date:	26-06-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	08-12-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC

Not approved

Date:	01-12-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2014-000173-39-NL
CCMO	NL46306.048.14