Anakinra versus treatment as usual in the treatment of acute gout // Anakinra versus standaardbehandeling bij acute jicht

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28223

Source
NTR

Brief title
ATTACG

Health condition

acute gout, anakinra, interleukin-1, pain, acute jicht, pijn, urate-lowering therapy

Sponsors and support

Primary sponsor: prof. dr. M.A.F.J. van de Laar
Source(s) of monetary or material Support: ZonMW, Sobi

Intervention

Outcome measures

Primary outcome

Change in patient-reported pain in the index joint from baseline to the average of pain values

at 24, 48, 72 hours

Secondary outcome

• Time to 50% reduction in pain in the primary affected joint

• Time to remission of pain

• Time to first reoccurrence of flare

• Number of new flares

• Decrease of primary joint swelling according to patient across day 2-5

• Decrease of primary joint tenderness according to patient across day 2-5

• Decrease in C-reactive protein (CRP) levels after 7 days of treatment

• Decrease of serum uric acid concentration after 3 months

• Treatment response according to patient across day 2 -7

• % dropout due to adverse events (AE)

• % dropout due to serious adverse events (SAE)

• physical function

• Health related quality of life (HR-QOL)

• Experienced side effects

• Direct and indirect costs

• % patients starting with canakinumab treatment

• % patients with serum uric acid concentration ≤ 0.36 mmol/l

Study description

Background summary

Gout is a common form of inflammatory arthropathy, with hyperuricemia being the

predominant risk factor. The close relationship between gout and hyperuricemia has led to treatment strategies wherein both the acute gout flare and hyperuricemia are targeted simultaneously. Currently available treatment options for gout flares (colchicine, corticosteroids and NSAIDs) are frequently contraindicated or poorly tolerated by gout patients due to presence of significant multi-morbidity. Anakinra (Kineretâ) is an IL-1 receptor antagonist presently indicated for the treatment of rheumatoid arthritis and Cryopyrin-Associated Periodic Syndromes. At present, anakinra has been studied in a handful of case series and small open label studies for its clinical efficacy and safety in acute gout. The objective of this study is to demonstrate non-inferiority of anakinra compared with the standard options in the treatment of acute gout flares. Also, to compare the safety and cost per quality-adjusted life day between anakinra and standard options and to compare the 3 and 12 months clinical outcome of patients initially treated with anakinra versus standard options and starting urate lowering therapy.

Study design

Measurements take place at day 1-7, months 3, 6, 9 and 12

Pain intensity at the primary joint during treatment follow-up time will be assessed using a 5-point Likert scale (1 = none; 2 = mild; 3 = moderate; 4 = severe; 5 = extreme) and a 100mm visual analog scale (0 = no pain, 100 = worst imaginable pain). Also a numeric rating scale (NRS) will be used to measure pain intensity (0 = no pain at all until 10 = worst imaginable pain) at day 1 -7 and during the occurence of an acute gout flare.

Swelling and joint tenderness will be measured on a 5-point Likert scale at day 1 -7 and during occurence of another acute gout flare..

Global assessment of overall wellbeing will be assessed using a 10 point NRS (0 = worst imaginable health until 10 = best imaginable wellbeing) at day 1 -7 and during the occurence of another acute gout flare.

Physical functioning will be assessed using the Stanford Health Assessment Questionnaire Disability Index (HAQ-DI) at day 1, 7, month 3,6,9 and 12

HR-QOL will be assessed using the medical outcomes survey short form 36 (SF-36) at day 1, 7, month 3,6,9 and 12

Work productivity will be assessed using the Work Productivity and Activity Impairment Questionnaire (WPAI) at day 1, 7, month 3,6,9 and 12. The direct and indirect costs will be calculated from the work productivity and health care volumes questionnaire filled in by the patient.

Intervention

Intervention group:

generic name: anakinra, subcutaneous injections

dose: 100 mg/day

treatment duration: 5 days

Active control: (1 of the 3 treatment regimes)

1. generic name: colchicine

dose: 0.5 mg (2-3 dd)

duration: 90 days (for treatment gout flare and as prophylaxis when starting urate lowering therapy)

2. generic name: naproxen

dose: 500 mg (2dd)

duration: 90 days (for treatment gout flare and as prophylaxis when starting urate lowering therapy)

3. generic name: prednisolon

dose: 35 mg/day

duration: 5 days

Contacts

Public

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Eligibility criteria

Inclusion criteria

• At least 18 years of age

• Signed written informed consent.

• Identification of intracellular MSU crystals in primary joint through aspiration of joint

Exclusion criteria

• Absolute contra-indication for all available types of ULT (allopurinol, febuxostat and benzbromaron)

• Absolute contra-indication for anakinra (i.a. creatinine clearance rate < 30 ml/ minute

• Presence of liver disease that according to the treating physician precludes participation in the study

• Absolute contra-indication for all three of the possible SoC treatments (colchicine, naproxen, prednisolon)

• Known history of allergy or sensitivity to latex

• Current us of any ULT (ULT therapies are allopurinol, febuxostat and benzbromaron)

• Concurrent use of other IL-1 agents

• Pregnancy or lactation

• Women who are planning on becoming pregnant within the study period (12 months)

• Patients with active or recurrent bacterial, fungal or viral infection

• Patients using TNF inhibitors

• Patient has insufficient knowledge of the Dutch language for completing questionnaires independently

• Patient reports no to mild gout related pain

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-12-2015
Enrollment:	200
Type:	Anticipated

Ethics review

Positive opinion

Date:	25-06-2015
Application type:	First submission

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
NTR-new	NL5102
NTR-old	NTR5234
Other	METC Twente; EudraCT : P15-16; 2015-000696-27

Study results