Allopurinol TreatmenT And oxypurinol Concentrations in gouty patients: Knowing the therapeutic window.

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- Demonstrating an association between oxypurinol concentration and the chance of succesfull lowering of urate concentration in gouty patients (defined as reaching urate concentrations < 0,30 mmol/l)

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON33306

Source
ToetsingOnline

Brief title
ATTACK

Condition

- Other condition

Synonym
gout

Health condition

Aandoening van het bewegingsapparaat

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Centrum Leeuwarden
Source(s) of monetary or material Support: eigen middelen.

Intervention

Keyword: allopurinol, gout, oxypurinol, TDM

Outcome measures

Primary outcome

- association between oxypurinol concentration and the chance on succesfull

treatment of gout (defined as

reaching urate concentrations of <0,30 mmol/l)

Secondary outcome

- association between oxypurinol concentration and the risk of getting adverse

drug reactions

- association between oxypurinol concentration and the chance on succesfull

treatment of gout (defined as

reaching urate concentrations of <0,36 mmol/l)

- percentage of patients succesfully treated with the proposed dosage nomogram

- the role of genetic variations on the occurence of adverse reactions

Study description

Background summary

Treatment of gouty patients with allopurinol is contemporary on basis of the applying guidelines. Allopurinol is well-thought-of in treating gout. When urate lowering is insufficient allopurinol dosage should be raised untill the maximum dosage of 900 mg per day. Own research shows that only 25% of gouty patients is succesfull in reaching urate concentration <0,30 mmol/l with an

allopurinol dosage of 300 mg per day.
The active metabolite of allopurinol is oxypurinol. The registration holder of allopurinol advises to measure the oxypurinolconcentration in case of impaired renal function. The oxypurinolconcencentration should be beneath 15,2 mg/l to avoid adverse effects. Common practice shows that oxypurinolconcentrations are seldom measured.

Study objective

- Demonstrating an association between oxypurinol concentration and the chance of succesfull lowering of urate concentration in gouty patients (defined as reaching urate concentrations < 0,30 mmol/l)

Study design

Patients diagnosed with gout and being treated with allopurinol are included. Dosing of allopurinol based on a dose nomogram for patients with impaired renal function. De dosage varies from 100 - 600 mg per day. Two and four months after starting allopurinol oxypurinolconcentrations and serumurate are measured.

Study burden and risks

not applicable

Contacts

Public
Medisch Centrum Leeuwarden

H. dunantweg 2
8934 AD
NL
Scientific
Medisch Centrum Leeuwarden

H. dunantweg 2
8934 AD
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Confirmed gout with urate crystals or tophi
2. First treatment with allopurinol
3. Filled and signed informed consent

Exclusion criteria

1. Patients younger than 18 years and pregnant women
2. Patients with eGFR <20 ml/min
3. Patients using azathioprine, mercaptopurine or cyclofosfamide
4. patients with elevated liverenzymes, defined as more than twice baseline ASAT or ALAT values

Study design

Design

Study phase:	4
Study type:	Observational invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	09-06-2009
Enrollment:	70
Type:	Actual

Medical products/devices used

Product type:	Medicine
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	09-06-2009
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

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	EUCTR2009-011260-10-NL
CCMO	NL27230.099.09