Biochemical efficacy and tolerability of allopurinol, benzbromarone and probenecid in gout.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25101

Source
NTR

Brief title
GOUT-1

Health condition

gout, hyperuricemia

Sponsors and support

Primary sponsor: drs M.K. Reinders
Department of Clinical Pharmacy and Pharmacology,
Medical Centre Leeuwarden
Postbox 888
8901 BR Leeuwarden
The Netherlands
Source(s) of monetary or material Support: fund = initiator = sponsor

Intervention

Outcome measures

Primary outcome

Success rate on study medication consisting of patient tolerability and attainment of target level serum urate <0.30 mmol/l after 8 weeks treatment.

Secondary outcome

1. Serum urate lowering effect (% decrease) of the antihyperuricemic agent;

2. tolerability of the antihyperuricemic agent (adverse drug reactions).

Study description

Background summary

1. To study the efficacy and tolerability of the uricostatic agent allopurinol 300 mg/day to decrease serum-urate to target values of <0.30 mmol/l in gout patients (stage 1).

2. To compare the efficacy and tolerability of the uricosuric agents benzbromarone 200 mg/day and probenecid 2000 mg/day to decrease serum urate to target values <0.30 mmol/l in gout patients inadequately treated with allopurinol (stage 2).

Study objective

1. Allopurinol has a poor efficacy and tolerability profile to lower serum urate to target levels <0.30 mmol/l.

2. Benzbromarone is more potent and is better tolerated than probenecid to lower serum urate to target levels <0.30 mmol/l.

Study design

N/A

Intervention

stage 1: allopurinol 1dd 300mg (8 weeks).

stage 2:

A. benzbromarone 1dd 200mg (8 weeks);

B. probenecide 2dd 1000mg (8 weeks).

Contacts

Public
Medical Centre Leeuwarden
Department of Clinical Pharmacy and Pharmacology
Postbox 888
M.K. Reinders
Leeuwarden 8901 BR
The Netherlands
0031 58 2866610
Scientific
Medical Centre Leeuwarden
Department of Clinical Pharmacy and Pharmacology
Postbox 888
M.K. Reinders
Leeuwarden 8901 BR
The Netherlands
0031 58 2866610

Eligibility criteria

Inclusion criteria

1. Age >18 year;

2. Diagnosis gout based on crystal evidence or ARA criteria;

3. Eestimated creatinine clearance >50 ml/min;

4. Baseline values measured: serum urate, urinary urate excretion, serum creatinine.

Exclusion criteria

1. Contra-indication for allopurinol, benzbromaron or probenecid;

2. Prior treatment with allopurinol, benzbromaron or probenecid.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-06-2005
Enrollment:	96
Type:	Actual

Ethics review

Positive opinion

Date:	12-02-2007
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	NL886
NTR-old	NTR901
Other	: N/A
ISRCTN	ISRCTN21473387

Study results

Summary results
N/A