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
Nationaal Trial Register

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

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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