

Biochemical efficacy and tolerability of allopurinol, benzbromarone and probenecid in GOUT

Submission date 26/02/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 26/02/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 08/02/2008	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title

Acronym

GOUT-1

Study objectives

1. Allopurinol has a poor efficacy and tolerability profile to lower serum urate to target levels less than 0.30 mmol/l
2. Benzbromarone is more potent and is better tolerated than probenecid to lower serum urate to target levels less than 0.30 mmol/l

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received by the Medical Centre Leeuwarden on the 7th February 2005 (ref: TPO-357).

Study design

Randomised, active controlled, parallel group, multicentre trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Hyperuricemia, gout

Interventions

Stage 1: allopurinol 1dd 300 mg (eight weeks)

Stage 2:

1. Benzbromarone 1dd 200 mg (eight weeks), or
2. Probenecide 2dd 1000 mg (eight weeks)

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Allopurinol, benzbromarone, probenecide

Primary outcome(s)

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

Key secondary outcome(s)

1. Serum urate lowering effect (% decrease) of the antihyperuricemic agent
2. Tolerability of the antihyperuricemic agent (adverse drug reactions)

Completion date

31/05/2007

Eligibility

Key inclusion criteria

1. Aged greater than 18 years
2. Diagnosis gout based on crystal evidence or American Rheumatism Association (ARA) criteria
3. Estimated creatinine clearance more than 50 ml/min
4. Baseline values measured: serum urate, urinary urate excretion, serum creatinine

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Not Specified

Key exclusion criteria

1. Contra-indication for allopurinol, benzbromaron or probenecid
2. Prior treatment with allopurinol, benzbromaron or probenecid

Date of first enrolment

01/06/2005

Date of final enrolment

31/05/2007

Locations

Countries of recruitment

Netherlands

Study participating centre

Medical Centre Leeuwarden

Leeuwarden

Netherlands

8901 BR

Sponsor information

Organisation

Medical Centre Leeuwarden (The Netherlands)

ROR

<https://ror.org/0283nw634>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Medical Centre Leeuwarden (The Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results	01/01/2009		Yes	No