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

Submission date	Recruitment status	[ ] Prospectively registered
26/02/2007	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
26/02/2007	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
08/02/2008	Musculoskeletal Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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 measure
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.

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

Overall study start date
01/06/2005

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. Eestimated creatinine clearance more than 50 ml/min
4. Baseline values measured: serum urate, urinary urate excretion, serum creatinine

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
96

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)

Sponsor details
Department of Clinical Pharmacy and Pharmacology
P.O. Box 888
Leeuwarden
Netherlands
8901 BR

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/0283nw634

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Medical Centre Leeuwarden (The Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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