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Biochemical efficacy and tolerability of allopurinol 300 - 600 mg/day versus benzbromarone 100 - 200 mg/day in GOUT patients

Submission date 26/02/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 26/02/2007	**Overall study status** Completed	
Last Edited 27/10/2022	**Condition category** 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
NTR903

Study information

Scientific Title
Biochemical efficacy and tolerability of allopurinol 300 - 600 mg/day versus benzbromarone 100 - 200 mg/day in GOUT patients

Acronym
GOUT-2

Study objectives
Attainment of target serum urate levels seems more succesful with benzbromarone 100 mg/day than with allopurinol 300 mg/day. We study whether allopurinol 600 mg/day provides a better success rate in attaining target serum urate levels.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Medical Centre Leeuwarden on the 13th March 2006 (ref: TPO-412).

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
Arm A: 1dd 300 mg allopurinol, when serum urate exceeds 0.30 mmol/L after eight weeks, dosage is increased to 2dd 300 mg
Arm B: 1dd 100 mg benzbroamrone, when serum urate exceeds 0.30 mmol/L after eight weeks, dosage is increased to 1dd 200 mg

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Allopurinol, benzbroamrone

Primary outcome measure
Success on study medication: tolerability and attainment of serum urate less than 0.30 mmol/L

Secondary outcome measures
1. Relative decrease of serum urate
2. Adverse drug reactions profile
3. Pharmacokinetic analysis of serum oxipurinol levels

Overall study start date
01/09/2006

Completion date
31/12/2007

Eligibility

Key inclusion criteria
1. Diagnosis based on crystal evidence or otherwise meeting the American Rheumatology Association (ARA) criteria
2. Baseline serum urate measured
3. Baseline urinary urate excretion measured
4. Estimated creatinine clearance more than 50 mL/min

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
60

Total final enrolment
65

Key exclusion criteria
1. Contra-indication for study medication: allopurinol or benzbromarone
2. Poor compliance on allopurinol defined as serum oxipurinol less than 5 mg/L

Date of first enrolment
01/09/2006

Date of final enrolment
31/12/2007

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
Not provided at time of registration

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		01/06/2009		Yes	No