

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

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| 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 27/10/2022 | 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

Contact name

Dr M K Reinders

Contact details

Medical Centre Leeuwarden
Department of Clinical Pharmacy and Pharmacology
P.O. Box 888
Leeuwarden
Netherlands
8901 BR
+31 (0)58 286 6610
m.reinders@znb.nl

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 benzbromarone, 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, benzbromarone

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

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 |