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

Submission date	Recruitment status No longer recruiting	Prospectively registered		
26/02/2007		☐ Protocol		
Registration date 26/02/2007	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited 27/10/2022	Condition category Musculoskeletal Diseases	Individual participant data		
21/10/2022	MIUSCUIOSKEIELAI DISEASES			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number 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 successful 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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s))

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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)

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

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