ISRCTN21473387 https://doi.org/10.1186/ISRCTN21473387

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

Submission date
26/02/2007

Recruitment status
No longer recruiting

Registration date
26/02/2007

Overall study status
Completed

Last Edited
08/02/2008

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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

Protocol serial number
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

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. Eestimated 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