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Pharmacokinetics of 6-thioguanine

Submission date 27/02/2007	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 27/02/2007	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 27/02/2007	**Condition category** Digestive System	[ ] Individual participant data [ ] Record updated in last year

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

Study objectives
Oral 6-thioguanine (6TG) results in a high intra-hepatic exposure to 6TG generated metabolites.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee

Study design
Non-randomised, non-controlled, clinical trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Irritable Bowel Syndrome (IBS), Ulcerative colitis, Crohn's Disease

Interventions
Patients will receive both 6TG orally and intravenously. On set times (for eight hours) blood will be drawn to determine the concentrations of different metabolites and enzymes.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
6-thioguanine

Primary outcome(s)
Determination of first pass effect of 6TG metabolites.

Key secondary outcome(s))
Determination of influence of different enzymes on 6TG metabolism.

Completion date
01/06/2006

Eligibility

Key inclusion criteria
1. Irritable Bowel Disease (IBD)
2. In need of immunosuppressants
3. Intolerant to azathioprine or methotrexate

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

Key exclusion criteria
1. Concomitant use of drugs interfering with thiopurine metabolism
2. Pregnancy/lactation

Date of first enrolment
01/06/2005

Date of final enrolment
01/06/2006

Locations

Countries of recruitment
Netherlands

Study participating centre
VU University Medical Centre
Amsterdam
Netherlands
1007 MB

Sponsor information

Organisation
VU University Medical Centre (VUMC) (The Netherlands)

ROR
https://ror.org/00q6h8f30

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
VU University Medical Centre (VUMC) (The Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration