

Pharmacokinetics of 6-thioguanine

Submission date 27/02/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 27/02/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 27/02/2007	Condition category Digestive System	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

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