

The influence of 5-aminosalicylates in thiopurine metabolite levels

Submission date 12/09/2005	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 12/09/2005	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 16/09/2008	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
NTR109

Study information

Scientific Title

Acronym

5-ASA-AZA

Study objectives

5-Aminosalicylates influence the metabolism of thiopurines leading to higher levels of the pharmacological end-metabolite 6-thioguaninenucleotides

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from local medical ethics committees

Primary study design

Interventional

Study design

Multicentre, randomised controlled trial

Study type(s)

Screening

Health condition(s) or problem(s) studied

Inflammatory bowel disease, ulcerative colitis, Crohn's disease

Interventions

Co-administration of 5-ASA (2 g/4 g/0 g followed by frequent blood draws.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

5-Aminosalicylates

Primary outcome(s)

The rise or fall in thiopurine metabolite levels

Key secondary outcome(s)

Safety

Completion date

01/01/2006

Eligibility

Key inclusion criteria

Steady state thiopurine therapy

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

Key exclusion criteria

1. Active disease
2. Comedication that may influence thiopurine metabolism
3. Pregnancy/lactation

Date of first enrolment

01/07/2005

Date of final enrolment

01/01/2006

Locations**Countries of recruitment**

Netherlands

Study participating centre

Gastroenterology & Hepatology

Amsterdam

Netherlands

1007 MB

Sponsor information**Organisation**

Vrije University Medical Centre (VUMC) (The Netherlands)

ROR

<https://ror.org/00q6h8f30>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Vrije University Medical Centre (VUMC) (The Netherlands) - Department of Gastroenterology and Hepatology

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Not provided at time of registration