ISRCTN71092125 https://doi.org/10.1186/ISRCTN71092125

The influence of 5-aminosalicylates in thiopurine metabolite levels

Submission date	Recruitment status	[ ] Prospectively registered
12/09/2005	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
12/09/2005	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
16/09/2008	Digestive System	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mr K.H.N. de Boer

Contact details
Gastroenterology & Hepatology
VU Medical Centre
P.O. Box 7057
Amsterdam
Netherlands
1007 MB
KHN.deBoer@vumc.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Multicentre, randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet

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 measure
The rise or fall in thiopurine metabolite levels

Secondary outcome measures
Safety

Overall study start date
01/07/2005

Completion date
01/01/2006

Eligibility

Key inclusion criteria
Steady state thiopurine therapy

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
24

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)

Sponsor details
Department of Gastroenterology and Hepatology
P.O. Box 7057
Amsterdam
Netherlands
1007 MB

Sponsor type
Hospital/treatment centre

Website
http://www.vumc.nl

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration