5-ASA-AZA study.

No registrations found.

Ethical review Positive opinion

Status Recruitment stopped

Health condition type -

Study type Interventional

Summary

ID

NL-OMON27677

Source

NTR

Brief title

5-ASA-AZA

Health condition

inflammatory bowel disease, crohn's disease and ulcerative colitis

Sponsors and support

Primary sponsor: investigator initiated

Source(s) of monetary or material Support: -

Intervention

Outcome measures

Primary outcome

The rise or fall in thiopurine metabolite levels.

Secondary outcome

Safety.

Study description

Background summary

IBD patients on steady state thiopurine receive three regimes of 5-ASA. During these periods blood will be drawn on set times to evaluate the metabolite levels.

Study objective

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

Intervention

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

Contacts

Public

VU University Medical Center, Department of Gastroenterology and Hepatology, P.O. Box 7057 K.H.N. Boer, de Amsterdam 1007 MB The Netherlands

Scientific

VU University Medical Center, Department of Gastroenterology and Hepatology, P.O. Box 7057
K.H.N. Boer, de
Amsterdam 1007 MB
The Netherlands

Eligibility criteria

Inclusion criteria

Steady state thiopurine therapy.

Exclusion criteria

- 1. Active diseas;
- 2. Comedication that may influence thiopurine metabolism;
- 3. Pregnancy/lactation.

Study design

Design

Study type: Interventional

Intervention model: Other

Masking: Open (masking not used)

Control: N/A, unknown

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 01-07-2005

Enrollment: 24

Type: Actual

Ethics review

Positive opinion

Date: 03-08-2005

Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

RegisterIDNTR-newNL78NTR-oldNTR109Other: N/A

ISRCTN ISRCTN90526229

Study results

Summary results

N/A