

# Long term toxicity of azathioprine (Imuran), 6-mercaptopurine (Purinethol) and 6-thioguanine (Lanvis) on the liver in inflammatory bowel disease patients.

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Pending
<b>Health condition type</b>	-
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON22783

### Source

NTR

### Brief title

LONGTOX

### Health condition

Inflammatory bowel disease, azathioprine, 6-mercaptopurine, 6-thioguanine, hepatotoxicity, liver biopsy.

Chronisch inflammatoir darmlijden, azathioprine, 6-mercaptopurine, 6-thioguanine, levertoxiciteit, leverbiopsie.

## Sponsors and support

**Primary sponsor:** Department of Gastroenterology and Hepatology, VU University Medical Center, Amsterdam, The Netherlands

**Source(s) of monetary or material Support:** fund=initiator=sponsor

## Intervention

## Outcome measures

### Primary outcome

Histopathologically proven nodular regenerative hyperplasia or sinusoidal dilatation.

### Secondary outcome

1. Ratio of [6-mercaptopurine nucleotides] and [6-thioguanine nucleotides];
2. Liver test abnormalities;
3. Demographic information.

## Study description

### Background summary

Thiopurines, such as azathioprine, 6-mercaptopurine and 6-thioguanine are increasingly used in the treatment of the inflammatory bowel diseases Crohn's disease and ulcerative colitis. Thiopurine therapy, 6-thioguanine therapy in particular, has been related with the occurrence of hepatotoxicity. At present there are no studies in which the hepatotoxicity of these thiopurines are being compared by means of histopathological evaluation. This study will give more insight in the hepatotoxicity of these drugs in inflammatory bowel disease patients, which may have implications for the long-term use of these drugs.

### Study objective

Long-term use of 6-thioguanine is more hepatotoxic, based on histopathological findings, as compared with the long-term use of azathioprine and 6-mercaptopurine in inflammatory bowel disease patients.

### Study design

After identification and when written informed consent is obtained, patients will visit the hospital once for the above mentioned interventions.

### Intervention

1. Liver biopsy;

2. Venapuncture;
3. Abdominal ultrasonography;
4. Physical examination;
5. A questionnaire.

## Contacts

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## Eligibility criteria

### **Inclusion criteria**

1. 18 to 70 years of age;
2. Diagnosed with Crohn's disease or ulcerative colitis;
3. Five to ten years use of one type of thiopurine succesively;
4. Obtained written informed consent.

### **Exclusion criteria**

1. Prior use of azathioprine or 6-mercaptopurine more that one year if using 6-thioguanine;

3 - Long term toxicity of azathioprine (Imuran), 6-mercaptopurine (Purinethol)and 6- ... 6-05-2025

2. Alanine aminotransferase, aspartate aminotransferase or alkaline phosphatase above twice the upper limit of the normal range;
3. Contraindications for core needle liver biopsy (ascites, suspected malignancy, anemia, low platelet count, prolonged prothrombin time);
4. Pregnancy;
5. (History of) alcohol abuse;
6. Incapacitated.

## Study design

### Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

### Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	10-01-2009
Enrollment:	114
Type:	Anticipated

## Ethics review

Positive opinion	
Date:	07-09-2009
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

Register	ID
NTR-new	NL1878
NTR-old	NTR1992
Other	METC VUMC : 09/030
ISRCTN	ISRCTN wordt niet meer aangevraagd.

## Study results

### Summary results

N/A