

# A 6-thioguanine (6-TG) registry that explores the effectiveness and safety of 6-TG in the long-term treatment of inflammatory bowel disease (IBD)

**First published:** 01/04/2016

**Last updated:** 03/05/2021

Study

Finalised

## Administrative details

### EU PAS number

EUPAS13007

### Study ID

40856

### DARWIN EU® study

No

### Study countries

☐ Netherlands

## Study description

Thiosix has been granted conditional approval by the regulatory authorities of the Netherlands. One of the conditions under which this approval was granted was to conduct a study that would further support the long-term efficacy and safety in a maintenance indication. Monitoring of all types of safety aspects by prospectively following-up patients using Thiosix is the objective of this study. The incidence of clinically confirmed NRH is the main concern and therefore the primary objective of this study.

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## Study status

Finalised

## Research institutions and networks

### Institutions

**Amsterdam UMC**

**First published:** 01/02/2024

**Last updated:** 01/02/2024

**Institution**

**Educational Institution**

**Hospital/Clinic/Other health care facility**

AUMC Netherlands, Maxima MC Netherlands, UMC Groningen Netherlands, UMC Utrecht Netherlands, Radboud UMC Netherlands, Meander MC Netherlands, Maasstad Netherlands, Isala

## Contact details

### Study institution contact

Curavista Curavista info@curavista.nl

Study contact

[info@curavista.nl](mailto:info@curavista.nl)

### Primary lead investigator

K.H.N De Boer

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Actual: 26/02/2016

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### Study start date

Planned: 01/04/2016

Actual: 12/05/2016

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### Data analysis start date

Actual: 14/12/2020

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### Date of interim report, if expected

Actual: 22/12/2017

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## **Date of final study report**

Planned: 01/05/2021

Actual: 01/05/2021

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Teva Nederland BV

## Regulatory

### **Was the study required by a regulatory body?**

Yes

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### **Is the study required by a Risk Management Plan (RMP)?**

EU RMP category 2 (specific obligation of marketing authorisation)

## Methodological aspects

### Study type

### Study type list

### **Study topic:**

Human medicinal product

Disease /health condition

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**Study type:**

Non-interventional study

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**Scope of the study:**

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

**Data collection methods:**

Primary data collection

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**Main study objective:**

Monitoring of the incidence of NRHExamine the safety of treatment with 6-  
thioguanineFollow-up on long-term efficacy of 6- thioguanine  
treatmentMonitoring of patient reported outcomes

## Study Design

**Non-interventional study design**

Other

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**Non-interventional study design, other**

Prospective non-interventional registry

## Study drug and medical condition

**Anatomical Therapeutic Chemical (ATC) code**

(L01BB03) tioguanine

tioguanine

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**Medical condition to be studied**

Inflammatory bowel disease

## Population studied

**Short description of the study population**

Inflammatory bowel disease (IBD) patients using Thiosix.

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**Age groups**

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

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**Special population of interest**

Immunocompromised

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**Estimated number of subjects**

87

## Study design details

## Outcomes

Incidence of histologically confirmed NRH within the first 12 months of the study, Incidence of ADRs,SAEs,signs of liver toxicity/clinically relevant changes in lab data, clinical signs of NRH/non-cirrhotic portal hypertensionClinically relevant abnormalities in blood countTotal duration of 6-TG treatmentProportion of pts in remission at various treatment durationsInd. changes from baseline of HBI,SCCAI at various time points% terminating due to surgery,time to surgery

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## Data analysis plan

Safety analysis data set contains all subjects who received 6-TG and have at least one record entry in the database. For quantitative parameters, descriptive statistics will be presented, i.e. mean, median, standard deviation, minimum and maximum. These statistics can relate to observed values, always including LOCF (last observation carried forward) endpoint visit, as well as to changes from baseline, including changes from baseline to each visit and LOCF endpoint.

# Data management

## Data sources

### Data sources (types)

[Other](#)

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### Data sources (types), other

Prospective patient-based data collection

## Use of a Common Data Model (CDM)

## CDM mapping

No

## Data quality specifications

### Check conformance

Unknown

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### Check completeness

Unknown

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### Check stability

Unknown

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### Check logical consistency

Unknown

## Data characterisation

### Data characterisation conducted

No