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

PURI

https://redirect.ema.europa.eu/resource/40856

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.

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 Netherlands

Contact details

Study institution contact

Curavista Curavista

Study contact

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

Study start date

Planned: 01/04/2016

Actual: 12/05/2016

Data analysis start date

Actual: 14/12/2020

Date of interim report, if expected
Actual: 22/12/2017

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

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

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Data collection methods:

Primary data collection

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

Non-interventional study design, other

Prospective non-interventional registry

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(L01BB03) tioguanine

tioguanine

Medical condition to be studied

Inflammatory bowel disease

Population studied

Short description of the study population

Inflammatory bowel disease (IBD) patients using Thiosix.

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)

Special population of interest

Immunocompromised

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

---

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

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

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No