A 6-thioguanine (6-TG) registry that explores the effectiveness and safety of 6-TG in the treatment of inflammatory bowel disease (IBD) in 6-TG naïve patients.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON21729

Source
NTR

Brief title
TS-001

Health condition

IBD patients, inadequately responding (lack of response and/or intolerance) to standard thiopurine therapy, naïve on 6-TG treatment.

Sponsors and support

Primary sponsor: None
Source(s) of monetary or material Support: Teva Pharmaceuticals Industries

Intervention

Outcome measures

Primary outcome

Maintenance of remission (HBI < 5 or SCCAI ≤ 2) without surgery throughout at least 12 months allowing 1 time additional corticosteroid use for a maximum duration of 3 months.

Secondary outcome

The proportion of patients in whom remission (HBI < 5 or SCCAI ≤ 2) is maintained with one course of corticosteroid for a maximum of 3 months without surgery throughout at least 6 months.
• The proportion of patients in whom steroid–free remission (HBI < 5 or SCCAI ≤ 2) is maintained without surgery throughout at least 12 months.
• The proportion of patients in whom remission, as determined by HBI < 5 or SCCAI ≤ 2, CRP < 10 mg/l, FCP < 100 microg/g faeces (or < upper normal limit of the test used) with one course of corticosteroid for a maximum of 3 months is maintained without surgery throughout at least 12 months.
• The proportion of patients in whom remission, as determined by the physician, with one course of corticosteroid for a maximum of 3 months is maintained without surgery throughout at least 12 months.

Study description

Background summary

- Examine the effectiveness of 6-thioguanine for maintenance treatment in 6-TG naïve UC and CD patients
- Examine the effectiveness of the current dosing scheme for 6-thioguanine in 6-TG naïve IBD patients
- Compare the effectiveness of 6-TG with effectiveness of methotrexate (MTX) in CD patients (historical matched control)
- Characterize the IBD patient population for which 6-thioguanine maintenance therapy is beneficial
- Monitoring of ADRs, SAE, signs of liver toxicity and NRH during 6-TG maintenance treatment in 6-TG naïve IBD patients
- Monitoring of patient reported outcomes (PRO)

Study objective

6-TG will be a beneficial therapy in about two-thirds of IBD patients whom failed previous therapies, consistent with the literature.

Study design

Efficacy at 6 months, sustained clinical efficacy within 12 months.

Contacts

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Eligibility criteria

Inclusion criteria

1. IBD diagnosis, according to current ECCO guidelines for at least 3 months (UC is characterised by diffuse mucosal inflammation limited to the colon; CD is characterised by patchy, transmural inflammation which may affect any part of GI tract).
2. Eligible for starting with 6-TG (formulated as Thiosix) treatment according to the treating physician.
3. The subject must have signed the ICF voluntarily before data is entered in the study database, after having been informed about the purpose of the study and by whom and in what way his/her medical and treatment data will be used.

Exclusion criteria

1. Patients younger than 18 years
2. Breastfeeding women
3. Previously demonstrated clinically significant allergy or hypersensitivity to the study drug or to any of the excipients of the medication
4. Patients using 6-TG in another formulation than Thiosix
5. Patients who have not used AZA or 6-MP prior to 6-TG treatment
6. Patients using 6-TG in combination with TNF-alpha inhibitors, ustekinumab or vedolizumab

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-07-2015
Enrollment:	104
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	25-02-2019
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	NL7551
Other	METc VUmc : 2016.181

Study results