The effects of THIOpurine therapy on SEMEN quality in IBD patients: a prospective cohort study

No registrations found.

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

Summary

ID

NL-OMON23373

Source
NTR

Brief title
THIO-SEMEN

Health condition

Inflammatory bowel diseases
Crohn's disease
Ulcerative colitis
Thiopurines
Fertility
Paternal exposure

Sponsors and support

Primary sponsor: TEVA Pharmaceuticals B.V.
Source(s) of monetary or material Support: TEVA Pharmaceuticals B.V.

Intervention

Outcome measures

Primary outcome

Differences in semen quality defined as sperm density, motility, morphology, ejaculation volume and total sperm count, prior to and during thiopurine exposure

Secondary outcome

The influence of thiopurines on paternally exposed offspring in terms of adverse pregnancy and birth outcomes (pre-term birth, low-birth weight, spontaneous abortions, congenital anomalies).

Study description

Background summary

Thiopurines are widely used immunosuppressive agents. In high dosages, they inhibit the purine synthesis and are considered to be possibly harmful to spermatogenesis, and subsequently to men’s fertility and their offspring. However, the clear association between thiopurine exposure and male fertility and reproduction safety, if any, is still poorly understood.

Appropriate counselling with regard to fertility, conception, and the possible effects of paternal thiopurine use, is essential in the management of IBD in potential fathers. Therefore the main objective of this study is to assess the effects of thiopurine exposure on the quality of semen in IBD-patients.

Study objective

The hypothesis is that patients with thiopurine therapy will not be at risk of impaired semen quality.

Study design

Sperm quality before and during at least 3 months thiopurine therapy will be assessed.

Intervention

None

Patients will start thopurines regarding treatment of inflammatory bowel diseases

Contacts

Public
Department of Gastroenterology and Hepatology, VU University Medical Centre Amsterdam

M. Simsek
Amsterdam
The Netherlands
+31 (0)20 444 07 99
Scientific
Department of Gastroenterology and Hepatology, VU University Medical Centre Amsterdam

M. Simsek
Amsterdam
The Netherlands
+31 (0)20 444 07 99

Eligibility criteria

Inclusion criteria

All male Crohn’s disease or ulcerative colitis patients, aged between 18 and 50 years who will be treated with thiopurines, without prior exposure to thiopurines or possible spermatotoxic drugs

Exclusion criteria

Subject with prior treatment with thiopurines in three months before inclusion, prior treatment with possible spermatotoxic drugs (e.g. sulfasalazine, tacrolimus, busulfan, chlorambucil, cyclophosphamide, cyclosporine) or male patients with a known history of subfertility or infertility.

Study design

Design

Study type: Observational non invasive

Intervention model:	Crossover
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2017
Enrollment:	30
Type:	Anticipated

Ethics review

Positive opinion

Date:	25-07-2018
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	NL7197
NTR-old	NTR7396
Other	METC VUmc : 2017.041

Study results

Summary results

The Association between Thiopurines and Male Fertility: a systematic review and meta-analysis