

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

Gepubliceerd: 25-07-2018 Laatste bijgewerkt: 18-08-2022

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

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON23373

Bron

NTR

Verkorte titel

THIO-SEMEN

Aandoening

Inflammatory bowel diseases

Crohn's disease

Ulcerative colitis

Thiopurines

Fertility

Paternal exposure

Ondersteuning

Primaire sponsor: TEVA Pharmaceuticals B.V.

Overige ondersteuning: TEVA Pharmaceuticals B.V.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

None

Patients will start thopurines regarding treatment of inflammatory bowel diseases

Contactpersonen

Publiek

Department of Gastroenterology and Hepatology, VU University Medical Centre Amsterdam

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

Wetenschappelijk

Department of Gastroenterology and Hepatology, VU University Medical Centre Amsterdam

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

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Cross-over
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-01-2017
Aantal proefpersonen:	30
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	25-07-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7197

Register

NTR-old

Ander register

ID

NTR7396

METC VUmc : 2017.041

Resultaten

Samenvatting resultaten

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