

The Effect of Methotrexate on Fertility Parameters in Men with Immune Mediated Diseases

No registrations found.

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

Summary

ID

NL-OMON20969

Source

Nationaal Trial Register

Brief title

iFAME-MTX

Health condition

Immune-mediated diseases such as Rheumatoid Arthritis (RA), Spondyloarthropathies (SpA), Juvenile Idiopathic Arthritis (JIA), Undifferentiated Arthritis (UA), Psoriasis (PsO), eczema (E) and Crohn's Disease (CD).

Sponsors and support

Primary sponsor: Erasmus MC

Source(s) of monetary or material Support: ReumaNederland

Intervention

Outcome measures

Primary outcome

To determine whether methotrexate (solely or as polyglutamate) can be quantified in seminal

fluid and spermatozoa of users.

Secondary outcome

Determine if there is a statistically significant difference on DNA Fragmentation Index between cases and study-controls.

Evaluate the associations between MTX concentration (solely or as polyglutamate) in seminal plasma and spermatozoa with those in serum and erythrocytes and with the traditional sperm quality measurements and the DNA Fragmentation Index.

Study description

Background summary

Rationale: Methotrexate (MTX) is the cornerstone in the treatment of several immune mediated diseases, such as Inflammatory Arthritis, Psoriasis and Crohn's Disease. Besides being teratogenic, MTX may also have a negative impact on sperm quality.

Recommendations for the use of MTX in men wishing to conceive are inconclusive, mainly because of the lack of studies about the impact of MTX on semen and spermatozoa.

Objective:

To determine whether MTX can be quantified in seminal plasma and spermatozoa of users and to evaluate the effect of MTX concentration on parameters of sperm quality, including the DNA fragmentation index (DFI).

Study design:

This is a case-control study. Twenty five adult male patients with immune mediated diseases (such as: rheumatoid arthritis, undifferentiated arthritis, spondyloarthropathies, juvenile idiopathic arthritis, psoriasis, eczema and Crohn's disease) who will start treatment with MTX will be included as cases. Specialists from several hospitals in the Rotterdam area will be involved in the recruitment of the cases. Twenty five adult healthy men will be recruited as study-controls. In cases, the MTX concentration in blood, seminal plasma and spermatozoa will be measured at baseline and 12 weeks later. Cases and study-controls will go through the same andrological evaluation, consisting of a physical examination, medical history, endocrine evaluation, semen quality analysis and DFI.

Main study parameters/endpoints:

To determine whether MTX can be quantified in seminal plasma and spermatozoa of users, and whether DFI is increased in relation to MTX.

Study objective

We hypothesize that MTX can be quantified in semen and that it is associated with measures of semen quality and DNA fragmentation

Study design

Not applicable

Intervention

Not applicable.

Contacts

Public

Erasmus MC
Luis Perez

06-50032378

Scientific

Erasmus MC
Luis Perez

06-50032378

Eligibility criteria

Inclusion criteria

Cases

- Males 18 years or older.
- Diagnosed with an immune mediated disease such as:

1. Rheumatoid Arthritis (RA)
2. Spondyloarthropathies (SpA)
3. Ankylosing Spondylitis (AS)
4. Psoriasis (PsO)
5. Eczema (E)

- MTX-naïve patients (i.e. no MTX treatment in the six months before inclusion) who will start MTX therapy (oral and subcutaneous routes of administration are allowed).
- Proven fertility, i.e. the man impregnated a woman (positive pregnancy test) in the past or who has biological children of his own (self-report).
- Able to give informed consent.

Study-controls

- Males 18 years or older.
- Proven fertile i.e. the man impregnated a woman (positive pregnancy test) in the past or who has biological children of his own (self-report).
- Able to give informed consent.

Exclusion criteria

Cases

- Age above 50 years.
- Known infertility (Self-report).
- Current use of the following drugs: Methadone hydrochloride, Nitrofurantoin, Dapsone, Paroxetine, Fluvoxamine maleate, Nifedipine, Colchicine, Cortisone acetate, Dexamethasone, Methylprednisone, Prednisone (>7.5 mg/day), Sulfasalazine, Triamcinolone hexacetonide, Busulfan, Chlorambucil, Cyclophosphamide, Dabrafenib, Degarelix, Fludarabine, Mercaptopurine, Procarbazine, Triptorelin, Vinblastine, Vinorelbine, Testosterone.
- Current sexually transmitted disease (Self-report).
- Current lower urinary tract infection (Self-report).
- Active infection with Hepatitis B or C virus (Self-report).
- Human immunodeficiency virus (HIV) infection (Self-report).
- Vasectomy.
- Language barrier.

Study design

Design

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

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	22-02-2019
Enrollment:	50

Type: Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date: 20-05-2020

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	NL8674
Other	METC Erasmus MC : MEC-2018-082

Study results