THL-olie pilot

Gepubliceerd: 11-06-2020 Laatst bijgewerkt: 15-05-2024

We hypothesize that the fertility enhancing effect of OSCM during HSGs is also present during THL.

Ethische beoordeling	Goedgekeurd WMO
Status	Werving gestopt
Type aandoening	Ovarium- en eileideraandoeningen
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON29484

Bron
Nationaal Trial Register

Verkorte titel
THL-olie pilot

Aandoening

- Ovarium- en eileideraandoeningen

Aandoening

50 subfertile women who showed tubal patency of at least one tube at THL.

Betreft onderzoek met
Mensen

Ondersteuning

Primaire sponsor: Board of Management Máxima MC
Overige ondersteuning: Wetenschapsfond Màxima MC

Onderzoeksproduct en/of interventie

- Overige

Toelichting

Uitkomstmaten

Primaire uitkomstmaten

The primary objective of this pilot study is to determine the feasibility of additional flushing of the fallopian tubes with Lipiodol Ultra Fluid, in terms of; the appearance of the oil at the tubal fimbriae, the appearance of mucus debris from the tubal fimbriae and the pain and acceptability scores of the patients.

Toelichting onderzoek

Achtergrond van het onderzoek

Subfertility is one of life’s great misfortunes. 10-15% of couples seek specialist fertility care at least once during their reproductive lifetime. The three most frequent causes of subfertility are sperm defects, ovulation disorders, and tubal pathology. Over the last decade, transvaginal hydrolaparoscopy (THL) has been introduced as the method of the first choice for tubal testing in the fertility workup in four teaching hospitals in the Netherlands. However, THL denies a possible treatment effect of oil-soluble contrast media (OSCM). Such a treatment effect of hysterosalpingography (HSG) with OSCM has been debated since 1965, until a recent large randomised controlled trial (RCT) showed that HSG with OSCM resulted in higher live birth rates. Implementation of the use of OSCM, namely Lipiodol® Ultra Fluid, is limited as in many clinics HSG has been replaced by other first line tests for tubal pathology, including hysterosalpingocontrast/foam sonography (HyCoSy/HyFoSy) and THL. The feasibility of additional tubal flushing with Lipiodol® Ultra Fluid after tests such as THL is however still unclear.

Doel van het onderzoek

We hypothesize that the fertility enhancing effect of OSCM during HSGs is also present during THL.

Onderzoeksopzet

Baseline, 4 weeks, 6 months (in case of pregnancy within 6 months after delivery)

Onderzoeksproduct en/of interventie

After tubal patency has been established, women will undergo flushing of the fallopian tubes with OSCM additionally to the regular water-based methylene-blue tubal flushing at the THL.

Contactpersonen

Publiek

Màxima MC
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040-8888384

Wetenschappelijk

Màxima MC
Inez Roest

040-8888384

Deelname eisen

Leeftijd
Volwassenen (18-64 jaar)
Volwassenen (18-64 jaar)
65 jaar en ouder
65 jaar en ouder

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Age > 18 years - Subfertility, defined as lack of conception despite 12 months of unprotected intercourse - Tubal patency of at least one Fallopian tube

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Pregnancy - Chlamydia-infection, an acute pelvic inflammation - Immobile uterus not allowing THL - Women with an uterus in retroversion flexion, as a THL is not feasible in these women - Masses or cysts in the pouch of Douglas or ovarian cysts, interfering with THL - Iodine allergy - Allergy for methylene blue or oil containing contrast - Manifest thyroid dysfunction - Patients with traumatic injuries, recent major haemorrhage or bleeding (not including the menstruation) - The use of the following medicinal products: beta blockers, vasoactive substances, angiotensin-converting enzyme inhibitors, angiotensin-receptor blockers, interleukin II (IV route) - Male subfertility defined as a post-wash total motile sperm

count < 3 million spermatozoa/mL - Not willing or able to sign the consent form.

Onderzoeksopzet

Opzet

Fase onderzoek:	N.V.T.
Type:	Interventie onderzoek
Onderzoeksmodel:	Enkelvoudig
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	Historische controle groep
Doel:	Behandeling / therapie

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-07-2020
Aantal proefpersonen:	50
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Goedgekeurd WMO

Datum:	11-06-2020
Soort:	Eerste indiening
Toetsingscommissie:	METC Máxima Medisch Centrum

Postbus 7777
5500 MB Veldhoven
040 888 9528
metc@mmc.nl

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 49816
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8696
CCMO	NL67021.015.19
OMON	NL-OMON49816

Resultaten