Additional tubal flushing with Lipiodol Ultra fluid after the diagnosis of tubal patency at transvaginal hydrolaparoscopy: a pilot feasibility study in 50 patients

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

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Ovarian and fallopian tube disorders
Study type	Interventional

Summary

ID

NL-OMON29484

Source
Nationaal Trial Register

Brief title
THL-olie pilot

Condition

- Ovarian and fallopian tube disorders

Health condition

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

Research involving
Human

Sponsors and support

Primary sponsor: Board of Management Máxima MC
Source(s) of monetary or material Support: Wetenschapsfond Màxima MC

Intervention

- Other intervention

Explanation

Outcome measures

Primary outcome

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.

Secondary outcome

The secondary objectives are the number and nature of adverse events, the influence on the thyroid function of the mother and the off-spring, and the amount of oil contrast that is necessary per procedure. The ongoing pregnancy rate, live birth rate and the mode of conception (IVF vs non-IVF) will be compared to the results from a previous study (van Kessel et al.).

Study description

Background summary

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.

Study objective

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

Study design

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

Intervention
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.

Contacts

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Eligibility criteria

Age
Adults (18-64 years)
Adults (18-64 years)
Elderly (65 years and older)
Elderly (65 years and older)

Inclusion criteria

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

Exclusion criteria

- 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.

Study design

Design

Study phase:	N/A
Study type:	Interventional
Intervention model:	Single
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	Historical
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-07-2020
Enrollment:	50
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Approved WMO Date:	11-06-2020
Application type:	First submission
Review commission:	METC Máxima Medisch Centrum Postbus 7777 5500 MB Veldhoven 040 888 9528 metc@mmc.nl

Study registrations

Followed up by the following (possibly more current) registration

ID: 49816
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

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

Study results