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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To determine the feasibility of additional flushing of the fallopian tubes with Lipiodol after tubal testing with methylene-blue during THL.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Reproductive tract disorders NEC
Study type	Interventional

Summary

ID

NL-OMON49816

Source
ToetsingOnline

Brief title
Pilot THL-oil

Condition

- Reproductive tract disorders NEC

Synonym
childless, subfertility

Research involving
Human

Sponsors and support

Primary sponsor: Maxima Medisch Centrum
Source(s) of monetary or material Support: Wetenschapsfonds Maxima MC

Intervention

Keyword: HSG, Lipiodol, Subfertility, Tubal flushing

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 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., manuscript in progress).

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 after OSCM at Hysterosalpingography (HSG) has been debated since 1965, until a recent large randomised controlled trial showed that OSCM at HSG results in higher live birth rates. Implementation of the use of OSCM (Lipiodol®) is limited as in many clinics HSG has been replaced by other first line tests for tubal pathology, including hystero salpingo contrast sonography (HyCoSy/HyFoSy) and THL. The therapeutic effect of additional tubal flushing with Lipiodol® after tests such as THL is however still unclear.

Study objective

To determine the feasibility of additional flushing of the fallopian tubes with Lipiodol after tubal testing with methylene-blue during THL.

Study design

Single-centre clinical pilot study, at the Máxima Medical Center in the Netherlands.

Intervention

After tubal patency has been established with the installation of methylene-blue during the THL, women will undergo additional flushing of the fallopian tubes with Lipiodol (max 10mL).

Study burden and risks

Since Lipiodol has already been used at HSG, we do not expect additional risks or burdens from the study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Age > 18 years
- Subfertility, defined as lack of conception despite 12 months 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 a 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 type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-08-2020
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	10-06-2020
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	01-07-2020
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	19-08-2021
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 29484
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL67021.015.19
OMON	NL-OMON29484