OIL - BASED CONTRAST VERSUS WATER BASED CONTRAST MEDIA IN THE DIAGNOSIS OF TUBAL PATENCY AT HYSTEROSALPINGOGRAPHY

Published: 23-02-2009
Last updated: 19-03-2025

To determine whether flushing of the fallopian tubes is more effective with an oil based contrast medium or a water based contrast medium in terms of ongoing pregnancy.

Ethical review	Approved WMO
Status	Pending
Health condition type	Sexual function and fertility disorders
Study type	Interventional

Summary

ID

NL-OMON32658

Source
ToetsingOnline

Brief title
water versus oil

Condition

- Sexual function and fertility disorders

Synonym
tubal obstruction, uterus picture

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: hysterosalpingography, oil, water

Outcome measures

Primary outcome

ongoing pregnancy rates

Secondary outcome

live birth rate, miscarriages, ectopic pregnancy, pain score, coital frequency

before and after HSG, pregnancy leading to live birth.

Study description

Background summary

As stated by the authors of a Cochrane review from Luttjeboer et al 2007 *further robust randomized trials comparing oil-soluble versus water-soluble media should be undertaken and would be a useful further guide to clinical practice*. The aim of this study proposal is therefore to perform a large multicentre randomized controlled trial of flushing with oil-soluble versus water-soluble contrast media in women with a low a priory chance of tubal pathology. The outcome measure is a ongoing pregnancy rate after six months.

Study objective

To determine whether flushing of the fallopian tubes is more effective with an oil based contrast medium or a water based contrast medium in terms of ongoing pregnancy.

Study design

Randomized clinical study

Intervention

Hysterosalpingography eighter with oil- or waterbased contrast media.

Study burden and risks

The potential benefit of OSCM would be increased probability of pregnancy. The potential harm would be possible complications from the use of OSCM. As stated in the protocol, the current randomised trials do not provide a clear answer to this question.

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 between 18 and 39 years
* Subfertility of at least one year
* Chlamydia Antibody Titre (CAT) negative (MIF <1:64 or ELISA <1:1)
* Low risk for tubal pathology according to the medical history (Coppus et al., 2007)
* Valid indication for HSG in the fertility work-up or before intra uterine insemination treatment.

Exclusion criteria

* Endocrino-pathological disease as: Polycystic ovary syndrome, Cushing syndrome, adrenal hyperplasia, hyperprolactinemia, acromegaly, hypothalamic amenorrhea, hypothyroidy, diabetes mellitus type I.
* Known or high risk for tubal pathology, CAT positive (MIF titre > 1:64 or ELISA > 1.1)
* Known contrast (iodine) allergy
* Male subfertility defined as a post-wash total motile sperm count < 3 x106 spermatozoa/ml
* If not willing or able to sign the consent form.

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2011
Enrollment:	1080
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Generic name:	telebrix hystero en lipiodol

Ethics review

Approved WMO Date:	20-07-2009
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-07-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	07-11-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-03-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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: 23300
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
EudraCT	EUCTR2008-007878-38-NL
CCMO	NL26044.018.08
OMON	NL-OMON23300