H2Oil-timing: Tubal flushing with oil-based contrast during HSG in subfertile women: Is early flushing effective and costeffective as compared to delayed flushing?

Gepubliceerd: 01-08-2019 Laatst bijgewerkt: 15-05-2024

Our hypothesis is that tubal flushing at HSG with oil-based contrast incorporated in the fertility work-up will result in 10% more ongoing pregnancies and a shorter time to pregnancy, and thus reducing the need for ART and reducing costs.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23111

Bron
NTR

Verkorte titel
H2Olie-timing

Aandoening

Subfertility, tubal patency testing

Ondersteuning

Primaire sponsor: Amsterdam UMC, VUmc
Overige ondersteuning: ZonMw, Guerbet

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcome is time to live birth, calculated from positive pregnancy test and within 12 months after randomization.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: We hypothesize that direct tubal flushing with oil-based contrast at HSG incorporated in the fertility work-up results in 10% more ongoing pregnancies and a shorter time to pregnancy compared to delayed tubal flushing 6 months after fertility work-up is completed in women at low risk for tubal pathology, which will lead to a reduction in the need for expensive fertility treatments like IVF and/or ICSI, and will therefore be an effective andcost effective strategy.

Objective: The aim of this study is to determine whether direct tubal flushing with oil-based contrast at HSG incorporated in the fertility work-up results in 10% more ongoing pregnancies and a shorter time to pregnancy, which will therefore be effective and cost-effective compared to delayed tubal flushing 6 months after fertility work-up is completed in women at low risk for tubal pathology.

Study design: We plan a multicentre randomized controlled trial with an economic analysis alongside it. Infertile women at low risk for tubal pathology will be randomized to direct tubal flushing with oil-based contrast incorporated in the fertility work-up or delayed tubal flushing 6 months after fertility work-up is completed.

Study population: Infertile women under 39 years of age, who have a spontaneous menstrual cycle and at low risk for tubal pathology, undergoing fertility work-up.

Intervention: Direct tubal flushing with oil-based contrast at HSG as part of the fertility work-up compared to delayed tubal flushing 6 months after the fertility work-up is completed.

Main study parameters/endpoints: The primary outcome is time to live birth, calculated from positive pregnancy test and within 12 months after randomization. Our hypothesis is that tubal flushing at HSG with oil-based contrast incorporated in the fertility work-up will result in 10% more ongoing pregnancies and a shorter time to pregnancy, and thus reducing the need for ART and reducing costs.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: As we compare strategies (tubal flushing with oil-based contrast at HSG incorporated in the fertility work-up versus 6 months after completion of fertility work-up) that are already applied in current practice, no additional risks or burdens are expected from

the study.

Doel van het onderzoek

Our hypothesis is that tubal flushing at HSG with oil-based contrast incorporated in the fertility work-up will result in 10% more ongoing pregnancies and a shorter time to pregnancy, and thus reducing the need for ART and reducing costs.

Onderzoeksopzet

Follow-up 12 months

Onderzoeksproduct en/of interventie

Direct HSG with oil-soluble contrast, incorporated in the fertility workup (intervention). Delayed HSG with oil-soluble contrast 6 months after fertility workup (control).

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

In order to be eligible to participate in this study, women must meet all of the following criteria:

- Between 18-39 years of age
- Spontaneous menstrual cycle
- Perceived low risk for tubal pathology
- Undergoing fertility work-up

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Women with known endocrine disorders (e.g. the polycystic ovary syndrome, diabetes, hyperthyroidism and hyperprolactinemia)
- Ovulation disorders defined as less than eight menstrual cycles per year
- Iodine allergy
- Male subfertility defined as a post-wash total motile sperm count < 3 x10^6 spermatozoa/ml
- Not willing or able to sign the consent form

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	22-08-2019
Aantal proefpersonen:	554
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Toelichting
N/A

Ethische beoordeling

Positief advies

Datum:	01-08-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 52895
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7926
CCMO	NL62838.029.19
OMON	NL-OMON52895

Resultaten

Samenvatting resultaten
N/A