Waterhoudend contrast vs. oliehoudend contrast voor het doorspuiten van de eileiders tijdens een baarmoederfoto – Effecten op de schildklierfunctie van het kind

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON22260

Source
Nationaal Trial Register

Health condition

Neonatal thyroid function, HSG, iodine, H2Oil study, oil-based contrast, water-based contrast.

Sponsors and support

Primary sponsor: Amsterdam UMC, location VUmc
Source(s) of monetary or material Support: Amsterdam UMC, location VUmc

Intervention

Outcome measures

Primary outcome

Thyroid function defined as total T4 level and, if available, TSH and TBG levels in neonates born to mothers who had undergone HSG with water and oil-based contrast.

Secondary outcome

F.e. birth weight, time between HSG and pregnancy and the (current) use of thyroid medication (f.e. Thyrax, Euthyrox or Levothyroxine).

Study description

Background summary

In 2017, we published the H2Oil trial (NTR3270), this study showed 10% more ongoing pregnancies after the use of oil-based contrast at hysterosalpingography (HSG) during fertility work-up compared to the use of water-based contrast at HSG (Dreyer et al., 2017). As a consequence of this positive effect, tubal flushing with oil-based contrast at HSG is gaining popularity. Therefore, it is important to investigate possible maternal and neonatal side effects. In 2015, one study reported a higher chance of thyroid dysfunction in neonates born to mothers who had undergone HSG with oil-based contrast (Satoh et al., 2015). This study investigated the frequency of neonatal thyroid dysfunction after maternal HSG involving oil-based contrast and possible risk factors. They found a higher frequency of a positive CH screening test (2.4%) after HSG with oil-based contrast compared to the recall rates among first CH screening results in Tokyo, Japan (0.7%). They reported a significantly higher median dosage of oil-based contrast medium in the thyroid dysfunction group than the normal thyroid function group and a higher incidence of Congenital Hypothyroidism (CH) and Hyperthyrotropinemia (HT) in these newborns. This study advised that when infertile women undergo HSG with oil-based contrast the dosage should be as low as possible to minimize the risk of fetal or neonatal thyroid dysfunction. However, it is questionable whether the results of Satoh et al. can be applied to the general Dutch or Western population. This study was conducted in Japan and the iodine intake in Japan is approximately 3-4 times higher than the estimated iodine intake for adults and pregnant women in the Netherlands or Europe. This higher iodine intake is mostly explained by large seaweed consumption.
Since our study group performed the H2Oil trial, where women were randomly assigned to either oil-or water-based contrast medium HSG and data of ongoing pregnancies within 6 months was known, we want to do a follow-up study to investigate the thyroid function of the newborns conceived after HSG in the H2Oil study. In the Netherlands, every newborn are tested for a variety of diseases between 4 and 7 days post-partum, through a blood test assembled form the heel, so called heel prick test. In this test, the total T4 level is measured and in case of a low T4 level, TSH- and TBG-levels are screened/tested. All results of the heel prick test of newborns are collected by the Dutch National Institute for Public Health and the Environment (in Dutch: RIVM, Rijksinstituut Volksgezondheid en Milieu). We want to collect the results of all newborns conceived after and HSG in the H2Oil study.

The aim of this study is to answer the following questions:
- Does tubal flushing at HSG with oil- or water-based contrast influence neonatal thyroid function in neonates born after HSG (from the H2Oil study)?
- And if the answer is yes, is there a difference between neonatal thyroid function after the

use of water-based or oil-based contrast media during HSG?

Study objective

See summary.

Study design

08-01-2019 start inclusion
01-05-2019 withdrawal data from the RIVM
01-01-2020 publication

Intervention

All participants of the H2Oil follow-up (NTR6577) study who agreed with approach for future research and had a live birth will receive an information package from their treating physician by post, email or at their next visit, containing:
1. A letter with information about the results of the H2Oil study, information about the aim of the current study and contact information.
2. Informed consent form. To obtain data from the RIVM, first and last name, DOB, postal code and birth weight of their child are necessary.
The above will be sent by postal mailing in a closed envelope. Women will be asked to return the signed informed consent to the coordinating investigators. A pre-stamped return envelope will be included for this purpose. A reminder will be sent to the families in case the informed consent form is not returned after two weeks.
After receiving the signed informed consent and in case of participation, we will request the information from the RIVM.

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Eligibility criteria

Inclusion criteria

Neonates, born to mothers who participated in the H2Oil study and the H2Oil follow-up study, and were conceived within 6 months after an HSG with the used of oil- or water-based contrast.

Exclusion criteria

Neonates born to mothers who conceived beyond the 6 month follow-up of the H2Oil study.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-01-2019
Enrollment:	369
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	13-02-2019
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7526
Other	METc VUmc : METc VUmc 2018.463 (niet-WMO advies)

Study results