Contact and information

Prof. Dr. Diane De Neubourg
principal investigator of the site
+32 3 821 36 84

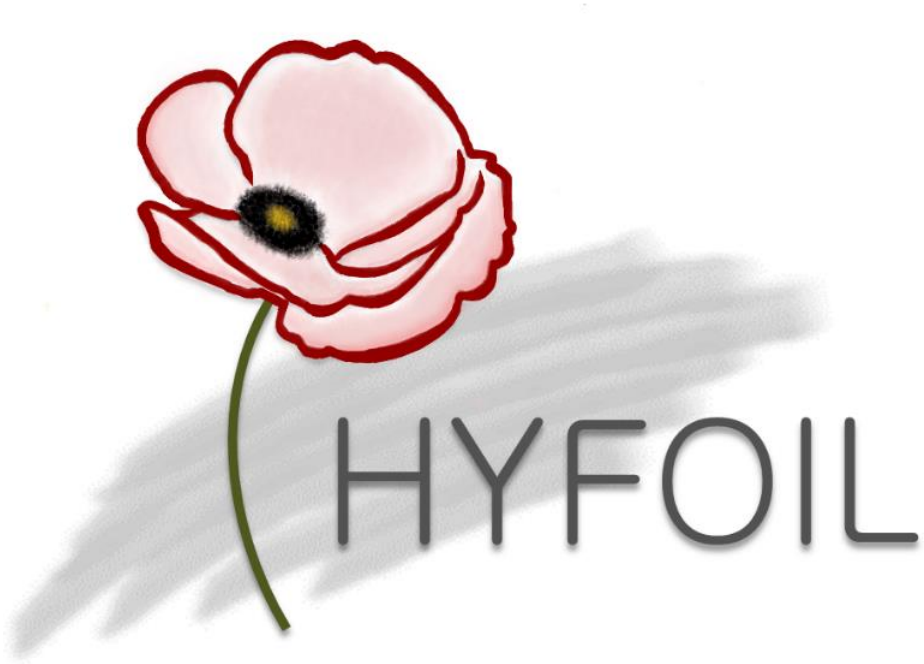
Lara Janssens
Elena Verheyden
study staff
+32 3 821 24 17

The study and this leaflet were approved by the Ethics Committee.

This leaflet contains general information and is intended to supplement the information provided by your healthcare professional.

UZA / Drie Eikenstraat 655 / 2650 Edegem
Tel + 32 3 821 30 00 / www.uza.be

A study concerning the influence of tubal flushing with oil on pregnancy and live birth in women with fertility problems



KCE
Federaal Kenniscentrum voor de Gezondheidszorg
Centre Fédéral d'Expertise des Soins de Santé
Belgian Health Care Knowledge Centre

Dear patient,

You are currently receiving treatment at our center. Do you meet the following conditions?

- Your doctor has prescribed a Hyfosy, an examination in which the permeability of the Fallopian tubes is checked during a vaginal ultrasound.
- You are between 18 and 40 years of age.
- You are undergoing treatment for one of the following reasons:
    - You have not developed a spontaneous pregnancy after at least 12 months of unprotected sexual intercourse;
    - You participate in an insemination program with donor sperm, where the three first cycles with donor insemination did not result in pregnancy;
    - You are being treated with ovulation induction for an ovulation disorder, where no pregnancy has occurred after three ovulatory cycles.

If so, we invite you to participate in a clinical study designed to evaluate a study medication.

What is the Hyfoil study?

The study will investigate the effect of the medication Lipiodol® Ultra Fluide (an oil-based contrast agent). It is a pragmatic study, which means that the intervention will be tested in daily practice. Thus, as few additional hospital appointments or examinations as possible will be scheduled.

You will receive a standard Hyfosy, in which a foamy contrast gel is inserted into the uterine cavity and Fallopian tubes to evaluate whether the tubes are permeable. If you participate in the study, you will have a 50% chance of receiving an additional flush with Lipiodol® Ultra Fluide immediately afterwards. You will also have a 50% chance of not receiving an additional flush. Which study group you end up in will be determined randomly. This is the only way we can objectively and convincingly demonstrate whether or not there is an effect.

Why is this study being performed?

With this study we want to invesigate whether flushing the Fallopian tubes with Lipiodol® Ultra Fluide leads to an increased chance of pregnancy and live birth.

We are doing this following a previous study, which showed that the chance of pregnancy and live birth was higher in women who received a flush with oil than in women who had their Fallopian tubes flushed with water. The percentage of pregnancies beyond 12 weeks rose from 29.1% to 39.7% and the percentage of live birth rose from 28.1 to 38.8%.

In the above study, the permeability of the Fallopian tubes was assessed under radiographic control. Currently, this examination is performed using ultrasound (Hyfosy), in which this effect has not yet been demonstrated.

This is the aim of this study: does the study medication have the same positive effect during a Hyfosy?

HYFOIL