# A study of the timing of intra-uterine insemination relative to ovulation.

No registrations found.

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|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Recruitment stopped |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON23163

**Source**
NTR

**Health condition**

Subfertility.
Subfertiliteit / verminderde vruchtbaarheid.

### Sponsors and support

**Primary sponsor:** Maastricht University Medical Center +
**Source(s) of monetary or material Support:** Maastricht University Medical Center +

### Intervention

### Outcome measures

#### Primary outcome

The main study parameter/endpoint is ongoing pregnancy rate, as defined as a pregnancy with fetal cardiac activity at ultrasound at 12 weeks of gestation, per IUI treatment strategy.

#### Secondary outcome

The secondary study parameters/endpoints are (ongoing) pregnancy rate per cycle, ongoing pregnancy rate per cause of subfertility, miscarriage rate, multiple pregnancy rate, live birth

rate and adverse events. Other study parameters/endpoints are the cost-effectiveness of both strategies, potential cost-savings in view of a reduction of the need for additional IUI cycles and IVF treatment and patient satisfaction and quality of life.

# Study description

**Background summary**

Rationale:

Intra-uterine insemination (IUI) combined with mild ovarian stimulation (MOS) and triggering of ovulation is a common treatment for subfertility, with pregnancy rates ranging between 7 and 12% per cycle. To couples who do not conceive after several cycles of IUI-MOS, In Vitro Fertilization (IVF) treatment is offered. The current practice in IUI-MOS is to administer human chorionic gonadotropin (hCG) for triggering ovulation when the largest follicle has reached a diameter of 16-18 mm, followed by IUI 32-36 hours later (i.e. around ovulation). However, studies on natural conception have proven that the maximum probability of pregnancy occurs with intercourse one day prior to ovulation. Therefore, it is hypothesized that IUI should be performed one day prior to ovulation (as triggered by hCG administration). Increasing the effectiveness of IUI-MOS would decrease the need for additional IUI-MOS cycles and IVF, and thereby would be cost-reducing.

Objective:

The main objective is to determine the effectiveness of IUI-MOS, comparing the ongoing pregnancy rate of a treatment strategy comprising a maximum of four cycles of IUI-MOS when performing IUI 32-36 hours after triggering of ovulation (“late IUI”) with performing IUI at the time of triggering of ovulation (“early IUI”). The secondary objective is to determine (ongoing) pregnancy rate per cycle and per cause of subfertility, miscarriage rate, multiple pregnancy rate, live birth rate and adverse events. The tertiary objective is to determine the cost-effectiveness of both strategies and the potential cost-savings in view of a reduction of the need for additional IUI-MOS cycles and IVF treatment. Condition-specific questionnaires will be used to determine patient satisfaction (PCQ-Infertility) and quality of life (FertiQoL).

Study design:

Multi-center open-labelled randomised controlled trial.

Study population:

Couples with unexplained subfertility, mild male factor subfertility and cervical factor subfertility and who are eligible for IUI-MOS.

Intervention:

In group one, IUI will be performed 32-36 hours after triggering of ovulation by hCG, which is administered when the largest follicle has reached a diameter of 16-18 mm (“late IUI”). In group two, IUI will be performed at the time of triggering of ovulation by hCG, which is on the day the largest follicle has reached a diameter of 16-18 mm (“early IUI”).

Main study parameters/endpoints:

The main study parameter/endpoint is the ongoing pregnancy rate per IUI-MOS treatment strategy.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

Because only timing of IUI will be different in the two study groups, no burden or risks are involved. No extra blood samples or extra visits are needed. During each cycle, all couples are asked to fill in a questionnaire about factors potentially influencing pregnancy rate (e.g. weight, smoking, natural intercourse during treatment).

## Study objective

Early intra-uterine insemination (IUI; at the time of triggering of ovulation) may result in higher pregnancy rates as compared to late IUI (32-36 hours after triggering of ovulation), thereby decreasing the need for additional cycles of IUI and in vitro fertilisation treatment.

## Study design

The primary outcome will be measured by ultrasound at 12 weeks of gestation in case of pregnancy (in case of non-pregnancy: At the end of the IUI treatment strategy).

The secondary outcomes will be measured in the same manner.

## Intervention

In group one, IUI will be performed 32-36 hours after triggering of ovulation by human chorionic gonadotropin (hCG), which is administered when the largest follicle has reached a diameter of 16-18 mm (“late IUI”).

In group two, IUI will be performed at the time of triggering of ovulation by hCG, which is on the day the largest follicle has reached a diameter of 16-18 mm (“early IUI”).

# Contacts

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# Eligibility criteria

## Inclusion criteria

Couples with unexplained subfertility, mild male factor subfertility and cervical factor subfertility who are eligible for IUI (estimated spontaneous pregnancy chance of <30% in the coming year, according to the prognostic model of Hunault) can be included. Only couples who are about to start IUI treatment, are eligible for this study.

## Exclusion criteria

In case of female age > 42 years old, female BMI > 35 kg/m2, double-sided tubal pathology

or severe male factor subfertility (< 1 million progressive motile sperm cells per sample in repeated semen analyses), the couple is excluded. Couples who have already undergone at least one IUI-MOS cycle, are not eligible for this study.

# Study design

## Design

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|---|---|
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Active |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 01-01-2013 |
| Enrollment: | 358 |
| Type: | Actual |

# Ethics review

Positive opinion

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|---|---|
| Date: | 15-10-2012 |
| Application type: | First submission |

# Study registrations

## Followed up by the following (possibly more current) registration

ID: 40074
Bron: ToetsingOnline
Titel:

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

No registrations found.

## In other registers

| Register | ID |
|---|---|
| NTR-new | NL3486 |
| NTR-old | NTR3666 |
| CCMO | NL39738.068.12 |
| ISRCTN | ISRCTN wordt niet meer aangevraagd. |
| OMON | NL-OMON40074 |

# Study results

**Summary results**
N/A