# Early versus late insemination relative to ovulation in subfertile couples: a trial-based cost-effectiveness study.

Published: 11-01-2012
Last updated: 15-05-2024

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Sexual function and fertility disorders |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON40074

**Source**
ToetsingOnline

**Brief title**
Early versus late insemination relative to ovulation.

### Condition

- Sexual function and fertility disorders

**Synonym**
Subfertility, unfulfilled childwish.

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Medisch Universitair Ziekenhuis Maastricht
**Source(s) of monetary or material Support:** Subsidie bij ZON-MW is aangevraagd.

## Intervention

**Keyword:** Intra-uterine insemination., Ovulation., Pregnancy rate., Timing.

## Outcome measures

### Primary outcome

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

### Secondary outcome

Ongoing pregnancy rate per cycle and per cause of subfertility, miscarriage rate, multiple pregnancy rate, live birth rate , adverse events, cost-effectiveness, cost-savings, budget impact resulting from a reduction of the need for additional IUI-MOS cycles and subsequent IVF-treatments, patient satisfaction and quality of life.

# Study description

### Background summary

Intra-uterine insemination (IUI) combined with mild ovarian stimulation (MOS) and triggering of ovulation by human chorionic gonadotropin (hCG) is a common treatment for subfertility, with pregnancy rates varying between 7 and 12% per cycle and estimated hospital costs of ¤ 850 per cycle (ESHRE Capri Workshop Group, 2009; Steures et al., 2009). To couples who do not conceive after several cycles of IUI-MOS, In Vitro Fertilization (IVF) treatment is offered, with pregnancy rates varying between 26 and 28% per cycle and estimated hospital costs of ¤4,500 per cycle (Fiddelers, 2010). The current practice in IUI-MOS is to administer hCG for triggering of ovulation when the largest follicle has reached a diameter of 16-18 mm, followed by IUI 32-36 hours later (i.e. around the expected time of ovulation). However, clinical studies to support this particular 32-36 hours interval between hCG and IUI are lacking (Ragni et al., 2004; Snick et al., 2008; Cantineau et al., 2010). Studies on natural conception have shown that the maximum probability of pregnancy occurs with intercourse one day prior to ovulation (Dunson et al., 1999). Therefore, it is hypothesized that IUI should be performed one day prior to ovulation as

triggered by hCG administration, rather than in the peri-ovulatory phase as is current practice. Increasing the effectiveness of IUI-MOS would decrease the need for additional IUI-MOS cycles and for subsequent IVF, resulting in substantial health care cost-savings.

### Study 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 by hCG (*late IUI*) with IUI at the time of triggering of ovulation by hCG (*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, cost-savings and budget impact resulting from a reduction of the need for additional IUI-MOS cycles and subsequent IVF treatment. Condition-specific questionnaires will be used to determine patient satisfaction (PCQ-Infertility) and quality of life (FertiQol).

### Study design

Multi-center open-label randomized controlled trial.

### Intervention

In group one (*late IUI*), 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. In group two ("early IUI"), 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.

### Study burden and risks

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).

## 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

Couples with unexplained subfertility, mild male factor subfertility and cervical factor subfertility are eligible for IUI according to the present Dutch national guidelines, and they will be offered inclusion in this study.

## Exclusion criteria

In case of female age > 40 years old, female body mass index > 30 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 will be excluded.

# Study design

## Design

**Study type:** Interventional

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| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Treatment |

## Recruitment

NL

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 13-02-2013 |
| Enrollment: | 358 |
| Type: | Actual |

# Ethics review

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| Approved WMO Date: | 31-10-2012 |
| Application type: | First submission |
| Review commission: | METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht) |
| Approved WMO Date: | 13-10-2014 |
| Application type: | Amendment |
| Review commission: | METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht) |

# 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: 23163

Source: NTR
Title:

## In other registers

| Register | ID |
|---|---|
| CCMO | NL39738.068.12 |
| Other | volgt |
| OMON | NL-OMON23163 |