Cost-effectiveness of IVF for unexplained or mild male subfertility in women from 38 years up. A multi-centre randomized controlled trial.

No registrations found.

Ethical review	Positive opinion
Status	Other
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26052

Source
NTR

Health condition

IVF, in vitro fertilization, unexplained infertility, advanced age, 38 years old, ovarian aging, in vitro fertilisatie, onverklaarde subfertiliteit, ovariele veroudering

Sponsors and support

Primary sponsor: Academic Medical Centre
Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

The primary outcome is ongoing pregnancy resulting in live birth, conceived within a period of 8 months after randomisation

Secondary outcome

Secondary outcomes are clinical pregnancy, multiple pregnancy, miscarriage, pregnancy complications, premature birth, couples¡¯ preferences, quality of life and costs. In a cost-effectiveness analysis, we will calculate incremental costs per ongoing pregnancy conceived within a time horizon of 8 months after randomisation comparing IVF to expectant management.

Study description

Study objective

Our hypothesis is that 8 months IVF results in 10% higher pregnancy rates leading to a live birth compared to 8 months expectant management.

Study design

a time horizon of 8 months after randomisation

Intervention

IVF treatment versus expectant management

Contacts

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Eligibility criteria

Inclusion criteria

- Age at least 38 and younger than 42 (women must be 38, 39, 40, or 41 at inclusion).

- Had unprotected regular intercourse during at least 12 months without conception.

- Normal regular ovulatory cycle between 26 and 34 days as confirmed by either history,

basal temperature curve, ultrasound monitoring or serum progesterone

- Tubal patency of at least one tube as established with either hysterosalpingography, contrastsonography, or diagnostic laparoscopy, or a confirmed earlier intra-uterine pregnancy (miscarriage or ongoing) not through IVF.

- Partners with normal or mildly impaired semen quality (TMSC ¡Ý 3 million).

Exclusion criteria

- Age <38 or >42 at the time of inclusion

- Irregular cycle, defined as < 25 days or >34 days.

- Double sided tubal occlusion

- Poor semen quality (TMSC <3 million)

- Couples undergoing IVF combined with Pre-implantation Genetic Diagnosis

- Couples undergoing ICSI combined with TESE (testiculair spermextraction)

- Couples undergoing IVF or ICSI with donor sperm

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Other
Start date (anticipated):	01-09-2015
Enrollment:	440
Type:	Unknown

Ethics review

Positive opinion

Date:	01-10-2015
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 50639
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5384

Register	ID
NTR-old	NTR5484
CCMO	NL42977.018.15
OMON	NL-OMON50639

Study results