Cost-effectiveness of IUI, IVF and ICSI for male subfertility. The MAle Subfertility Therapy Effectiveness Rcts.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24404

Source
NTR

Brief title
MASTER

Health condition

Male subfertility (mannelijke subfertiliteit), cost-effectiveness (kosteneffectiviteit), Expectant management (afwachtend beleid), IUI

Sponsors and support

Primary sponsor: Academic Medical Center (AMC)
Source(s) of monetary or material Support: ZON-MW, The Netherlands Organization for Health Research and Development

Intervention

Outcome measures

Primary outcome

Ongoing pregnancy leading to live birth within the treatment time horizon.

Secondary outcome

Time to pregnancy, miscarriage, multiple pregnancy and live birth rate are secondary outcomes. Further secondary outcomes are neonatal mortality, pregnancy complications (preterm birth < 37 weeks, birth weight < 2.500 gram, PIH, (pre-) eclampsia, HELLP) costs of reproductive treatments, perinatal care and ad-verse events. Also patients' quality of life and preferences will serve as secondary outcomes.

Study description

Background summary

Rationale:

We hypothesize that less invasive therapies are equally effective as more invasive therapies for male subfertility.

Objective:

In one third of subfertile couples male subfertility is diagnosed. Current treatments for male subfertility, IUI, IVF and ICSI, have, despite their widespread use, not been compared on their cost-effectiveness. The primary aim of this project is to assess the cost-effectiveness of therapies for male subfertility.

Study design:

IUI versus expectant management in mild male subfertility.

Study population:

Subfertile couples with pre-wash TMSC 6-10 million.

Intervention:

3 cycles of IUI, followed by 3 cycles of IUI-controlled ovarian hyper-stimulation (COH).

Control:

Expectant management (EM). Treatment time horizon 6 months.

Main study parameters/endpoints:

Primary: Ongoing pregnancy leading to live birth.

Secondary: Time to pregnancy, miscarriage, multiple pregnancy, live birth, perinatal outcome, (in-)direct costs, quality of life and patient preferences.

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

As we compare interventions that are already applied in current practice, no additional risks or burdens are expected from the study.

Study objective

To evaluate the cost-effectiveness of therapies for male subfertility.

Study design

Primary and secondary outcomes within 6 months after randomisation.

Intervention

3 cycles of IUI, followed by 3 cycles of IUI-COH versus expectant management.

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Eligibility criteria

Inclusion criteria

1. Age female partner: 18-38 years;

2. Failure to conceive: 12-36 months;

3. Male subfertility: Pre-wash TMSC 6-10.10^6.

Exclusion criteria

1. Severe male subfertility: Pre-wash TMSC < 6.10^6;

2. Female partner with polycystic ovary syndrome or any other anovulation, severe endometriosis, double-sided tubal pathology, endocrinopathological disease (Cushing syndrome, adrenal hyperplasia, hyperprolactinemia, acromegaly, imminent ovarian failure, premature ovarian failure, hypothalamic amenorrhea and diabetes mellitus (type I).

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2013
Enrollment:	340
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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	NL3632
NTR-old	NTR3820
Other	ZonMW : 837002003
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A