

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

Gepubliceerd: 14-01-2013 Laatste bijgewerkt: 18-08-2022

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

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27063

Bron

Nationaal Trial Register

Verkorte titel

MASTER study

Aandoening

ICSI, IVF, male subfertility (mannelijke subfertiliteit), cost-effectiveness (kosteneffectiviteit)

Ondersteuning

Primaire sponsor: Academic Medical Center (AMC)

Overige ondersteuning: ZON-MW, The Netherlands Organization for Health Research and Development

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcome is establishment of ongoing pregnancy leading to live birth within the treatment time horizon.

Toelichting onderzoek

Achtergrond van het onderzoek

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:

ICSI versus IVF in severe male subfertility.

Study population:

Subfertile couples with male subfertility (pre-wash TMSC <3 million, post-wash >300.000).

Intervention:

3 cycles of ICSI, including transfer of cryopreserved embryos.

Control: 3 cycles of IVF, including transfer of cryopreserved embryos. Treatment time horizon 12 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.

Doel van het onderzoek

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

Onderzoeksopzet

Primary and secondary outcomes within 12 months after randomisation. Questionnaires at one day, two months, four months and six months after randomization.

Onderzoeksproduct en/of interventie

3 cycles of ICSI, including transfer of cryopreserved embryos vs 3 cycles of IVF, including transfer of cryopreserved embryos.

Contactpersonen

Publiek

Postbus 90153
J.P. Bruin, de
Den Bosch 5200 ME
The Netherlands
+31 (0)73 6998660

Wetenschappelijk

Postbus 90153
J.P. Bruin, de
Den Bosch 5200 ME
The Netherlands

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Age female partner: 18-38 years;
2. Failure to conceive: 12-36 months;
3. Male subfertility: Pre-wash TMSC $< 3 \cdot 10^6$, Post-wash TMSC > 300.000 .

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Severe male subfertility: Pre-wash TMSC < 300.000 ;
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)).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland	
Status:	Werving nog niet gestart

(Verwachte) startdatum: 01-06-2013
Aantal proefpersonen: 380
Type: Verwachte startdatum

Ethische beoordeling

Niet van toepassing
Soort: Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3635
NTR-old	NTR3823
Ander register	ZonMW : 837002003
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A