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

Gepubliceerd: 26-01-2013 Laatst 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-OMON24404

Bron
NTR

Verkorte titel
MASTER

Aandoening

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

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

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:

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.

Doel van het onderzoek

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

Onderzoeksopzet

Primary and secondary outcomes within 6 months after randomisation.

Onderzoeksproduct en/of interventie

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

Contactpersonen

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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 6-10.10^6.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd

Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-06-2013
Aantal proefpersonen:	340
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	NL3632
NTR-old	NTR3820
Ander register	ZonMW : 837002003
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A