

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

Published: 03-04-2013

Last updated: 24-04-2024

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...

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

Summary

ID

NL-OMON39669

Source

ToetsingOnline

Brief title

MASTER study

Condition

- Sexual function and fertility disorders

Synonym

decreased male fertility, Male subfertility

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W, ZonMW

Intervention

Keyword: Cost-Benefit Analysis [MeSH], Infertility, Male [MeSH], Pregnancy rate [MeSH], Therapy [MeSH]

Outcome measures

Primary outcome

Ongoing pregnancy leading to live birth

Secondary outcome

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

Study description

Background summary

We hypothesize that less invasive therapies for male subfertility are cost-effective compare to more invasive therapies.

Study 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

Two parallel RCTs:

1. IUI versus expectant management in mild male subfertility.
2. ICSI versus IVF in severe male subfertility.

Intervention

RCT 1: 3 cycles of IUI, followed by 3 cycles of IUI-COH. Control: expectant

management. Treatment time horizon 6 months.

RCT 2: 3 cycles of ICSI, including transfer of cryoembryos. Control: 3 cycles of IVF, including transfer of cryopreserved embryos. Treatment time horizon 12 months.

Study burden and risks

Nature and extent of the burden and risks for the patients will be the same as they are with the treatments for male subfertility we use nowadays. Only to fill in some questionnaires the patients need some extra time compare to patients who will not participate in our study.

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

RCT 1:

- Male subfertility: Pre-wash TMSC $< 10 \cdot 10^6$ & $> 3 \cdot 10^6$
- Age female partner 18-42 years
- Failure to conceive for at least 12
- Couple who start treatment for a first, or first after a successful pregnancy, cycle

RCT 2

- Age female partner between: 18-42 years
- Male subfertility: Pre-wash TMSC $< 3 \cdot 10^6$
- Treatment naive or failure to conceive during IUI-treatment or first IVF/ICSI cycle after birth of a child

Exclusion criteria

RCT 1:

- 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))
- Major uterine or ovarian abnormalities detected by TVS which is classified as contraindication for pregnancy or medically assisted reproduction

RCT 2:

- Severe male subfertility: Post-wash TMSC $< 300 \cdot 10^3$
- Major uterine or ovarian abnormalities detected by TVS which is classified as contraindication for pregnancy or medically assisted reproduction

Study design

Design

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

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	13-05-2013
Enrollment:	830
Type:	Actual

Ethics review

Approved WMO	
Date:	03-04-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	12-04-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	13-05-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	07-06-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	18-06-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	05-07-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	10-07-2013

Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	19-08-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	04-09-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	06-09-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	17-09-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	28-11-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	11-12-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	07-01-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	05-03-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	14-03-2014

Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	16-04-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	07-05-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	13-05-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	07-07-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	26-08-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	09-09-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	19-09-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	24-10-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	30-10-2014

Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	10-11-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-01-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	02-10-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
CCMO	NL42194.018.13