

Patient-centred implementation of elective single embryo transfer (eSET) in in vitro fertilisation (IVF) and intracytoplasmic sperm injection (ICSI).

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·implementation objective(s)/research question(s): The main aim is to compare the effectiveness and costs of the implementation of elective single embryo transfer (eSET) in in vitro fertilisation (IVF) and intracytoplasmic sperm injection (ICSI),...

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON30404

Source

ToetsingOnline

Brief title

PITS, Patient centred Implementation Trial for Single embryo transfer

Condition

- Other condition

Synonym

Evaluation of assisted reproduction, Subfertility treatment

Health condition

Subfertiliteit, Paren die IVF/ICSI behandeling zullen ondergaan

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: Assisted reproduction, Implementation, Preventing twin pregnancies, Single embryo transfer (SET)

Outcome measures

Primary outcome

·outcome measures and process indicators: Main outcome measure is the eSET occurrence rate and cost-effectiveness of the combined strategy.

Secondary outcome

Secondary outcome measures are in the field of: 1) patient knowledge 2) patient decisional conflict 3) patient satisfaction and 4) IVF/ICSI treatment outcome.

Study description

Background summary

This trial will investigate the implementation of single embryo transfer (eSET). Implementation of eSET can be done through different strategies. Many of them have the disadvantage that patients lose the ability to choose themselves. They lose their autonomy to make their medical decisions. The goal of our study is to implement eSET with respect to the couple's autonomy to participate in shared decision making. Prior to this study, focusgroup interviews were held and the main conclusions were that the most important inhibiting factors are with the patient-couples. They seem uninformed about risks and complications of twin pregnancies and often have financial reasons to transfer more embryos at once. The design of our trial is to see if counselling with an evidence-based decision aid could raise the incidence for the choice for eSET. Furthermore we will also investigate if reimbursement of a (possible) 4th cycle has an effect on that incidence. In our study design the 4th cycle will be paid for if the couples have chosen for eSET in the first 2 cycles.

Study objective

·implementation objective(s)/research question(s): The main aim is to compare the effectiveness and costs of the implementation of elective single embryo transfer (eSET) in in vitro fertilisation (IVF) and intracytoplasmic sperm injection (ICSI), between usual care and a combined patient-centred strategy.

Study design

design: A randomised controlled trial is performed.

Intervention

intervention to be implemented: eSET in IVF/ICSI

Study burden and risks

The burden for participants could consist of the possible 4th IVF/ICSI treatment cycle. This is only applicable for couples who are not pregnant after 3 cycles and who have chosen SET in cycle 1 and 2.

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

Couples starting with their first IVF/ICSI cycle (with or without earlier successful treatment) with the female younger than 40 years.

Exclusion criteria

Medical necessity for SET. Female older than 39 years. Less than 2 embryos available for transfer in the first cycle.

Study design

Design

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

Primary purpose: Health services research

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-05-2006
Enrollment:	210
Type:	Anticipated

Ethics review

Approved WMO

Application type:

First submission

Review commission:

CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL11293.091.06