Is Rescue ICSI a useful tool in the routine IVF lab for patients undergoing total IVF fertilization failure?*

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Ethical review	Approved WMO
Status	Pending
Health condition type	Pregnancy, labour, delivery and postpartum conditions
Study type	Interventional

Summary

ID

NL-OMON57127

Source
ToetsingOnline

Brief title
R-ICSI

Condition

- Pregnancy, labour, delivery and postpartum conditions

Synonym
fertilization failure, unfertilized oocyte

Research involving
Human

Sponsors and support

Primary sponsor: Fertiliteitscentrum Voorburg, Reinier de Graaf Groep
Source(s) of monetary or material Support: zelf geïnitieerd onderzoek;wordt door Fertiliteitscentrum Voorburg;Reinier de Graaf Groep gefinancierd.

Intervention

Keyword: fertilization failure, oocyte, pregnancy, rescue icsi

Outcome measures

Primary outcome

The primary parameters/endpoints of this study are:

1. Ongoing pregnancy rate from fresh embryo transfers (ET) in patients that have been undergoing the R-ICSI procedure and

2. Ongoing pregnancy rate following transfers with frozen embryos (FET) in patients that have supernumerary embryos frozen from the same R-ICSI cycle and

3. Cumulative ongoing pregnancy (cOPR) rates in patients that have both fresh and frozen embryos as a result of the same R-ICSI cycle.

Secondary outcome

The following secondary endpoints of the study will be analysed: 4. fertilization rate after R-ICSI,

5. embryo usage rate (EUR) of embryos used for ET and cryopreservation after R-ICSI,

6. Pregnancy rate,

7. Implantation rate (IR) after transfer of fresh and/ or cryopreserved embryos after R-ICSI.

8. Further, a cost assessment will be incorporated in the results to assess whether R-ICSI implementation is financially more effective in place of an abandoned IVF cycle.

Study description

Background summary

Even though IVF in clinical practice has a long history going back to 1978 with considerable scientific breakthroughs since then, the incidence of unexpected total fertilization failure (TFF) after conventional IVF remains one of the most frustrating events for both patients and embryologists. In most cases, the etiology behind such an event is unexplained and unexpected.TFF is defined as the complete lack of fertilization at the standard checking time of 18-± 1 h post- insemination. This means that the obvious fertilization signs, female and male pronuclei, are not visible in any of the inseminated mature oocytes in the metaphase of meiosis II (MII) of the patient. The idea of rescue ICSI (R-ICSI) is not a new one; it consists in performing intracytoplasmatic sperm injection (ICSI) 18-24hours later on oocytes that following IVF insemination have shown no signs of fertilisation on the day after oocyte retrieval.
From the perspective of fertilization rate, pregnancies and live birth, the use of R-ICSI is supported in the literature. Arpit et al (2017), in their systematic review have concluded that although pregnancy rates are not as promising as fertilization rates, R-ICSI should be offered as an option to couples going through a total fertilization failure as it can result in the birth of healthy babies. A retrospective cohort study (Zhu et al., 2023) assessed the clinical outcomes of TFF cases, in a 10-year period, reported that all 215 new-borns out of the 1291 embryo transfers were reported healthy. Successful live births after use of R- ICSI have been worldwide reported. An economic analysis, comparing the group that did receive R-ICSI versus the group that abandoned the fresh cycle and started a new one, showed a 25% reduction in the costs involved per live birth when R-ICSI was applied. Cost-effectiveness of the R-ICSI procedure in terms of TFF was considered worthwhile (Shalom-paz et al., 2011).

Study objective

The main objective of this study is to evaluate whether the application of rescue ICSI (R-ICSI), to patients having a failed fertilization with a standard insemination procedure (IVF) can increase the chance of ongoing pregnancies either with the use of fresh or cryopreserved embryos that are the result of the intervention. The secondary objective is to assess the cost efficiency of the salvaged treatment compared to an abandoned IVF cycle.

Study design

The study is a pilot pre-post intervention clinical trial.

Intervention

We will compare the ongoing pregnancies between the pre intervention group (no R-ICSI) versus the post intervention group (R-ICSI).

Study burden and risks

The potential benefit for the patients is a possible chance for a fresh embryo transfer and therefore a chance of pregnancy compared to no chance at all. In the case there are supernumerary embryos in the same attempt, patients would profit from freezing any extra embryos of good quality for future use.
The associated burden for the patients participating in the study will probably involve an extra visit to the fertility centre with the purpose of providing a second sperm sample. If possible, and depending on the semen quality the day after oocyte recovery (OR), this step may be avoided. Following the second attempt to fertilize the oocytes, all treatment steps are given a 24-hour delay. The patients participating in the study will be asked to provide information to their IVF doctor regarding the outcome of their treatment (i.e. pregnancy, and live birth outcome). This procedure is standard in our centre for all IVF patients. No extra questionnaires need to be filled by the patients. There are no extra costs or compensation for the couples that decide to participate in this study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

In order to be eligible to participate in this study, the subjects must meet all the following criteria:
• Couple is eligible for IVF (normal semen parameters)
• Couple has read the Patient Information Folder (PIF) and signed the Informed Consent.
• Woman is 40 years of age or less at the time of treatment.
• Couple has at least 4 metaphase II (MII) oocytes with no visible 2nd polar body (PB) after the first fertilization check.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
• All couples that have at least one confirmed normally fertilised oocyte (2PN) and are eligible for a fresh embryo transfer.
• All couples that have less than four oocytes.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL
Recruitment status: Pending

Start date (anticipated):	01-01-2025
Enrollment:	18
Type:	Anticipated

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	22-11-2024
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

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	NL87384.000.24