ToF-studie
Embryo transfer, day Three Or day Five, in good prognosis IVF cycles.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23649

Source
NTR

Brief title
ToF

Health condition

Embryotransfer Day 3 vs Day 5
In Vitro Fertilization(IVF)
Cumulative live birth rate

Embryotransfer Dag 3 vs Dag 5
In Vitro Fertilisatie(IVF)
Cumulatief aantal levend geborenen

Sponsors and support

Primary sponsor: Radboud university medical center
Source(s) of monetary or material Support: Leading the Change/ZonMw

Intervention

Outcome measures

Primary outcome

The primary aim is to study whether blastocyst stage embryo transfers (day 5) improves the cumulative LBR in IVF/ ICSI patients with a good prognosis (> 3 zygotes on day 1 after oocyte retrieval).

Secondary outcome

1.) Parameters of IVF treatment: such as live birth rate per first transfer, time to pregnancy, cumulative live birth rate (> 24 weeks) per started IVF/ICSI cycle, implantation rate, miscarriage rate.

2.) Parameters of perinatal treatment: i.e. birth defects, perinatal mortality, preterm birth (< 2,5 kg), high birth weight (> 4kg), small for gestational age (< 10th percentile or < -2SD), large for gestational age (> 90th percentile or > + 2SD), placenta previa, placental abruption, placenta accreta, pregnancy-induced hypertension, preeclampsia/ HELLP, gestational diabetes mellitus, placental abruption, preterm rupture of membranes, postpartum hemorrhage, caesarean section, Apgar < 7 at 5 min, stillbirth per ongoing pregnancy.

3.) Patient outcome analysis: Quality-Adjusted Life-Years (EuroQol (EQ-5D-5L) and the Fertility Quality of Life Questionnaire (FertiQoL)).

4.) A cost-effectiveness analysis (CEA) will be performed from a healthcare perspective. A cost-utility analysis (CUA) will be performed to relate the burden of intervention to the transfer strategy

Study description

Background summary

Rationale: The last years there is an ongoing debate on which embryo transfer policy in IVF/ICSI is more effective: blastocyst stage (day 5) or cleavage stage (day 3) transfer.The cumulative live birth rate(LBR) after IVF/ICSI is expected to be 8% higher after blastocyst stage embryo transfers compared to cleavage stage embryo transfers. Furthermore, the time to pregnancy will be shorter and less expensive IVF/ICSI treatments are necessary.

Objective: To determine whether blastocyst stage embryo transfers improve the cumulative live birth rate compared with cleavage stage embryo transfers in IVF/ICSI treatments.

Study design: Multicentre Randomized controlled trial

Study population: Women under 43 years receiving a IVF/ICSI treatment.

Intervention: Blastocyst stage (day 5) embryo transfer

Comparison: Cleavage stage (day 3) embryo transfer

Main study parameters/endpoints: Cumulative live birth rate per started IVF/ICSI cycle, time to pregnancy, costs.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: The risk associated with the blastocyst transfer policy is a lower amount of embryos available for transfer or cryopreservation as some embryos will arrest in their development in vitro. The potential benefit is a higher chance of pregnancy and a shorter time to pregnancy with the blastocyst transfer policy, as valued by patients. There are no extra burdens, efforts or costs to be expected for the couples. Subjects who participate fill in questionnaires at the start and end of the study, as well as on the 4th month after ovum pick-up.

Study objective

The cumulative live birth rate after IVF/ICSI is expected to be 8% higher after blastocyst stage embryo transfers (day 5
compared to cleavage stage embryo transfers (day 3). Furthermore, the time to pregnancy will be shorter and less expensive
IVF/ICSI treatments are necessary.

Study design

The study endpoints for the subject are: after delivery, 12 months after the ovum pick up or when no pregnancy occurs after the IVF treatment cycle.

4 months after the ovum pick-up, a questionnaire concerning the quality of life is send to the subjects.

Intervention

Blastocyst stage (day 5) embryo transfer

Contacts

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Eligibility criteria

Inclusion criteria

Women 18-42 years

IVF/ICSI treatment with more than 3 zygotes on culture day 1 available.

Written informed consent

Exclusion criteria

The use of testicular sperm extraction (TESE), Preimplantation genetic diagnosis (PGD)cycles
The use of vitrified oocytes -Participating in interfering study.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-04-2018
Enrollment:	1200
Type:	Actual

IPD sharing statement

Plan to share IPD: Yes

Ethics review

Positive opinion

Date:	19-02-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 50232
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL6857
NTR-old	NTR7034
CCMO	NL64060.000.18
OMON	NL-OMON50232

Study results