Cumulative live birth rate after cleavage-stage(day three) or blastocyst stage(day five) embryo transfer in good prognosis IVF/ICSI cycles.

Published: 11-06-2018
Last updated: 07-12-2024

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

Ethical review	Approved WMO
Status	Completed
Health condition type	Neonatal and perinatal conditions
Study type	Interventional

Summary

ID

NL-OMON50232

Source
ToetsingOnline

Brief title
ToF study(Three Or Five)

Condition

- Neonatal and perinatal conditions
- Sexual function and fertility disorders

Synonym
Assisted reproduction, Infertility

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum

Source(s) of monetary or material Support: ZonMW Doelsmatigheidsonderzoek/ Leading the Change

Intervention

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

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 embryo's on day 2 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)),patient preferences.

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

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.

The present RCT will provide evidence which transfer policy leads to the best outcome in terms of cumulative live birth rate per
started IVF/ ICSI cycle. If blastocyst transfer is equally effective, the time to pregnancy, as valued by patients, will be shorter.
This would lead to a decrease in burden and could be more effective from a patient*s viewpoint, but even important to a
decrease in health insurance costs.

Study 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

Randomized controlled multi-center superiority trial with 12 months of follow-up

Intervention

Blastocyst stage (day 5) embryo transfer

Study burden and risks

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.

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

-Women 18-42 years

-IVF/ICSI treatment with at least 4 embryos on culture day 2 available.
-Written informed consent

Exclusion criteria

-Preimplantation genetic diagnosis (PGD)cycles
-The use of vitrified oocytes
-Participating in interfering study
-Patients can only participate one IVF-cycle
-The use of donated oocytes

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:	Completed
Start date (anticipated):	28-08-2018
Enrollment:	1200
Type:	Actual

Ethics review

Approved WMO

Date:	11-06-2018
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den

	Haag)
Approved WMO Date:	07-08-2018
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	12-12-2018
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	15-01-2019
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	23-05-2019
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	27-06-2019
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	08-08-2019
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	21-04-2020
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	16-07-2020

Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	16-11-2020
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	06-05-2021
Application type:	Amendment
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

ID: 23649
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL64060.000.18