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

Gepubliceerd: 19-02-2018 Laatst bijgewerkt: 15-05-2024

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…

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23649

Bron
Nationaal Trial Register

Verkorte titel
ToF

Aandoening

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

Ondersteuning

Primaire sponsor: Radboud university medical center
Overige ondersteuning: Leading the Change/ZonMw

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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).

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

Blastocyst stage (day 5) embryo transfer

Contactpersonen

Publiek

RadboudUMC, Voortplantinggeneeskunde

Simone Cornelisse
Geert Grooteplein-Zuid 10

Nijmegen 6525 GA
The Netherlands
024 361 6644

Wetenschappelijk

RadboudUMC, Voortplantinggeneeskunde

Simone Cornelisse
Geert Grooteplein-Zuid 10

Nijmegen 6525 GA
The Netherlands
024 361 6644

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Women 18-42 years

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

Written informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-04-2018
Aantal proefpersonen:	1200
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

Ethische beoordeling

Positief advies

Datum:	19-02-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 50232
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten