Microfluidic embryo culture.

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The blastocyst formation rate of frozen-thawed donated human pre-implantation embryos cultured in a microfluidic platform is higher than in a standard culture dish.

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

Samenvatting

ID

NL-OMON26411

Bron
Nationaal Trial Register

Aandoening

Assisted reproductive technologies help overcoming many causes of infertility, and are widely used all over the world. Unfortunately efficiencies of the current technologies remain relatively low with pregnancy rates of only 20-30% per embryo transfer. This may be due to the format of the culture (static drops covered with oil), culture parameters (e.g. medium composition), extensive manipulation of the embryos and the inability to identify the most viable embryo. Therefore new approaches are needed to improve in vitro culture conditions and increase take home baby rates.

Ondersteuning

Primaire sponsor: VUmc (VU University Medical Center)
Overige ondersteuning: GFI grant by Merck Serono

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The main study endpoint is the blastocyst formation rate on day 5, 28 hours after thawing, in both, the control and experimental group.

Toelichting onderzoek

Achtergrond van het onderzoek

Validation of a microfluidic platform for the pre-implantation culture of individual human embryos and their on-line assessment using an integrated multi-parametric approach: morphological criteria, oxygen consumption and metabolic activity.

Doel van het onderzoek

The blastocyst formation rate of frozen-thawed donated human pre-implantation embryos cultured in a microfluidic platform is higher than in a standard culture dish.

Onderzoeksopzet

The project will approximately take 18 months in total. Only the first and third steps of the project will involve the culture of frozen-thawed donated human embryos.

Onderzoeksproduct en/of interventie

Frozen-thawed human embryos are either cultured in standard culture dishes or in microfluidic systems which enable the collection of essential information on the development of the embryos.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Frozen-thawed donated human embryos of sufficient morphological quality will be included in the study. The following criteria have to be met after thawing:

1. Minimum number of blastomeres: 8 cells;

2. Maximum degree of fragmentation: 20%;

3. Maximum degree of atresia: 25%.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Embryos with insufficient morphological quality after thawing will be excluded from the study according to the criteria described above.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	14-08-2012
Aantal proefpersonen:	400

Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	21-02-2013
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3697
NTR-old	NTR3867
CCMO	NL38300.000.11
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A