Microfluidic embryo culture.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26411

Source
Nationaal Trial Register

Health condition

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.

Sponsors and support

Primary sponsor: VUmc (VU University Medical Center)
Source(s) of monetary or material Support: GFI grant by Merck Serono

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

The secondary study parameter is the morphology of each embryo at different time points. The percentage of embryos that reach each developmental stage will be recorded and analysed as secondary study endpoints. Furthermore we will assess how many embryos are suitable for embryo transfer one day after thawing according to standard laboratory criteria.

Study description

Background summary

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.

Study objective

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.

Study design

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.

Intervention

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.

Contacts

Public
Amstelveenseweg 601
D.C. Kieslinger
Amsterdam 1081 JC
The Netherlands
+31 (0)20 4442935
Scientific
Amstelveenseweg 601

D.C. Kieslinger
Amsterdam 1081 JC
The Netherlands
+31 (0)20 4442935

Eligibility criteria

Inclusion criteria

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%.

Exclusion criteria

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

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL
Recruitment status: Recruiting

Start date (anticipated):	14-08-2012
Enrollment:	400
Type:	Anticipated

Ethics review

Positive opinion Date:	21-02-2013
Application type:	First submission

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

Study results

Summary results
N/A