

Time-lapse monitoring in IVF and ICSI patients

No registrations found.

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

Summary

ID

NL-OMON24583

Source

NTR

Brief title

SelecTIMO

Health condition

Subfertility

Sponsors and support

Primary sponsor: VU University Medical Center Amsterdam

Source(s) of monetary or material Support: ZonMW Health Care Efficiency Research program grant

Co-financing: Merck Serono

Intervention

Outcome measures

Primary outcome

The main study parameters are the ongoing pregnancy rate of the first fresh SET and the cumulative ongoing pregnancy rate including the first fresh SET

and all subsequent cryo transfers from the same ovum pick up cycle within one year.

Secondary outcome

The following secondary and exploratory endpoints will be analyzed:

biochemical pregnancy rate and live birth rate after fresh SET, cumulative live birth rate, miscarriage rate, time to pregnancy, embryo morphology and number of usable embryos (ie embryos used for transfer or cryopreservation), morphokinetic parameters, pregnancy rates in three female age groups, cost-efficiency, outcome of manual time-lapse annotations.

Study description

Background summary

The SelectTIMO study is a multicenter, three-armed, randomized, controlled, double blind trial. It will establish whether the use of time-lapse monitoring for embryo culture and embryo selection can outperform routine morphological embryo culture and selection. Furthermore, this trial will reveal whether an improvement of the clinical outcome is mediated through the stable culture environment and/or optimized selection method using Eeva time-lapse Results.

Study objective

Embryo selection using the Geri+ time-lapse system in combination with the Eeva Test (Early Embryo Viability Assessment) will increase the (cumulative) ongoing pregnancy rate of IVF and ICSI patients and thereby balance

additional costs of TLM (time-lapse monitoring) equipment.

Study design

N/A

Intervention

A) Embryo selection based on Eeva Results and continuous culture in Geri+ incubator (Geri+Eeva complete) and B) Routine embryo selection based on morphology and continuous culture in Geri+ incubator (Geri culture only) will be compared to C) Routine embryo selection based on morphology and interrupted culture in Geri+ incubator (Control). Embryos in all three groups will be cultured in the Geri+ time-lapse incubator.

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

Women scheduled for a single embryo transfer (SET) during their first IVF or ICSI cycle at any of the participating IVF centers will be considered for inclusion.

Exclusion criteria

Patients with a double embryo transfer, a planned 'freeze all' cycle without a fresh embryo transfer, or participation in an interfering scientific study will not be included in the study. Patients who are treated with donor sperm or

donor oocytes will be excluded. Also patients scheduled for PGD or thawing of oocytes after vitrification will be excluded.

Study design

Design

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

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	15-06-2017
Enrollment:	1740
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion	
Date:	08-09-2015
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	NL5314
NTR-old	NTR5423
Other	CCMO : 843001602

Study results