Embryo selection using time-lapse monitoring in IVF and ICSI patients

Published: 22-12-2016
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Does embryo selection using time-lapse monitoring (TLM) with Eeva (Early Embryo Viability Assessment) improve the (cumulative) ongoing pregnancy rate after IVF & ICSI treatments?

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON47802

Source
ToetsingOnline

Brief title
SelecTIMO

Condition

- Other condition

Synonym
Assisted reproduction, Infertility

Health condition

Onvruchtbaarheid

Research involving
(Surplus) Embryos

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: ZonMW Doelmatigheidsonderzoek,Merck

Intervention

Keyword: Eeva, embryo selection, time-lapse, TLM

Outcome measures

Primary outcome

The main study parameters are the ongoing pregnancy rate of the fresh SET and the cumulative ongoing pregnancy rate including the fresh SET and all subsequent cryo transfers from the same ovum pick up cycle within one year.

Secondary outcome

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.

Study description

Background summary

Time-lapse monitoring (TLM) of embryo development has the potential to increase the success rate of medically assisted reproduction (MAR) through more stable culture conditions and/or optimized embryo selection procedures. Before clinical introduction in Dutch IVF centers can be recommended, it is essential to study whether TLM does indeed improve success rates and if so, whether this increase is mediated by the improved culture conditions and/or optimized embryo selection procedures.
We hypothesize that TLM will lead to a higher succes rate, thereby balancing additional costs of time-lapse equipment.

Study objective

Does embryo selection using time-lapse monitoring (TLM) with Eeva (Early Embryo Viability Assessment) improve the (cumulative) ongoing pregnancy rate after IVF

& ICSI treatments?

Study design

Multicenter, three-armed, randomized, controlled, double blind trial.

Intervention

A. Embryo selection based on Eeva TLM algorithm and continuous embryo culture (TLM complete)
B. Routine embryo selection based on morphology and continuous embryo culture (TLM culture only)
C. Routine embryo selection based on morphology and standard embryo culture and embryo assessments outside the incubator (control)

Study burden and risks

The risks related to this study are comparable to the risks of a conventional IVF treatment. Since it is unlikely that patients will be negatively affected by this study we would like to ask clearance of contracting an insurance for patients.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Inclusion criteria

1st, 2nd or 3rd IVF or ICSI cycle
Single embryo transfer (SET)

Exclusion criteria

Double embryo transfer (DET)
Planned 'freeze all' cycle without a fresh embryo transfer
Participation in an interfering study

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-06-2017
Enrollment:	1740

Type:	Actual

Medical products/devices used

Generic name:	Geri incubator in combination with Eeva Test: Early Embryo Viability Assessment
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	22-12-2016
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	15-03-2017
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	26-10-2017
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	20-11-2017
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	27-11-2017
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	04-09-2018
Application type:	Amendment

Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	18-10-2018
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	15-07-2019
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	13-01-2020
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

No registrations found.

In other registers

Register	ID
CCMO	NL55996.000.16

Study results

Date completed:	31-01-2022

Actual enrolment:	1731