The metabolomic profile of an embryo as selection criteria for embryo transfer in IVF or ICSI treatment: a randomised controlled clinical trial

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The main objective is to study pregnancy rates after using metabolomic profiling added to the selection of viable embryos by morphology, compared to using only morphology.

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

Summary

ID

NL-OMON35290

Source
ToetsingOnline

Brief title
Embryo selection by metabolomic profiling

Condition

- Other condition

Synonym
n/a

Health condition

embryologie

Research involving
(Surplus) Embryos

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: ZonMW,Molecular Biometrics LLC, New Jersey, USA

Intervention

Keyword: embryo metabolism, Near Infrared Spectroscopy, non-invasive embryo selection, Single Embryo Transfer

Outcome measures

Primary outcome

Live birth rate

Secondary outcome

Ongoing pregnancy rate

Study description

Background summary

The high multiple pregnancy rate caused by IVF treatment leads to a higher incidence of medical, perinatal and neonatal complications and hence to higher health care costs. Single Embryo Transfer (SET) is an effective way to minimize risks of multiple pregnancies. Only one embryo is transferred, so the selection of the embryo with an optimum implantation potential very important. Currently, embryo selection is mainly based on morphological criteria using light microscope analysis. Because of its limited predictive value for ongoing pregnancy, new selection tools are being sought-after. Previous study showed that non-invasive metabolomic profiling seem to provide a strong addition to the selection of viable embryos and may serve as a useful methodology for rapid, non-invasive embryo selection. We hypothesize that pregnancy rates may improve when a more sensitive and specific selection tool like metabolomic profiling of biomarkers of oxidative metabolism by Near Infrared (NIR) Spectroscopy is used.

Study objective

The main objective is to study pregnancy rates after using metabolomic profiling added to the selection of viable embryos by morphology, compared to

using only morphology.

Study design

Prospective, randomised, controlled, double blind trial.

Intervention

it is possible to select a different embryo compared to the conventional selection.

Study burden and risks

none: the patients will get a standard IVF or ICSI treatment, only the fluid in which the embryo was grown will be analised.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

the transfer of one embryo (single embryo transfer-SET)

Exclusion criteria

patients where a double embryo transfer (DET) is performed
patients with less than 2 embryos of similar morphology
patients are allowed to participate in the study for one IVF/ICSI cycle

Study design

Design

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

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-09-2008
Enrollment:	720
Type:	Actual

Ethics review

Approved WMO

Date:	30-10-2007
Application type:	First submission

Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	15-06-2011
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	NL17593.000.07