Embryo selection by metabolomic profiling.

No registrations found.

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

Summary

ID

NL-OMON20735

Source
Nationaal Trial Register

Brief title
N/A

Health condition

1. Metabolomic profiling;

2. embryo selection;

3. IVF;

4. single embryo transfer (SET).

Sponsors and support

Primary sponsor: VU University medical center
Division of reproductive medicine
Source(s) of monetary or material Support: Fund=initiator

Intervention

Outcome measures

Primary outcome

Life birth rate.

Secondary outcome

Ongoing pregnancy rate. Ongoing pregnancy is defined as a positive fetal heart beat at 12 weeks gestational age.

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

Ho: the life birth rate in patients after SET with only morphological embryo selection is equal to patients with metabolomic profiling added to morphological selection.
H1: the life birth rate in patients after SET with only morphological embryo selection is unequal to patients with metabolomic profiling added to morphological selection.

Study design

N/A

Intervention

One group will get the conventional embryo selection (morphology) prior to transfer and one group gets in addition to the morphological selection metabolomic profiling.

Contacts

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Eligibility criteria

Inclusion criteria

Patients with SET, at least two embryos of equal quality.

Exclusion criteria

1. Patients with DET (double embryo transfer);

2. patients with less than 2 embryos of equal quality;

3. patients can only be included for one IVF/ICSI cycle.

Study design

Design

Study type: Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2008
Enrollment:	370
Type:	Actual

Ethics review

Positive opinion

Date:	10-01-2008
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	NL1136
NTR-old	NTR1178
Other	VUmc : incomplete
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results

Day 3 embryo selection by metabolomic profiling of culture medium with near-infrared spectroscopy as an adjunct to morphology: a randomized controlled trial.
Vergouw CG, Kieslinger DC, Kostelijk EH, Botros LL, Schats R, Hompes PG, Sakkas D, Lambalk CB.
Hum Reprod. 2012 Aug;27(8):2304-11. doi: 10.1093/humrep/des175. Epub 2012 May 30.

No evidence that embryo selection by near-infrared spectroscopy in addition to morphology is able to improve live birth rates: results from an individual patient data meta-analysis.
Vergouw CG, Heymans MW, Hardarson T, Sfontouris IA, Economou KA, Ahlström A, Rogberg L, Lainas TG, Sakkas D, Kieslinger DC, Kostelijk EH, Hompes PG, Schats R, Lambalk CB.
Hum Reprod. 2014 Mar;29(3):455-61. doi: 10.1093/humrep/det456. Epub 2014 Jan 8.