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Can near infrared (NIR) spectroscopy of spent culture media from human embryos predict the embryos reproductive potential?

Submission date
02/07/2009

Recruitment status
No longer recruiting

Registration date
04/09/2009

Overall study status
Completed

Last Edited
18/04/2012

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
The use of near infrared (NIR) spectroscopy of culture media from human embryos to predict the embryos reproductive potential: a double-blinded randomised controlled trial

Study objectives

To find out if near infrared (NIR) spectroscopy of culture media from human embryos combined with morphology better predict an embryos reproductive potential than embryo morphology alone.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Local ethics committee (Regionala Etikprövningsnamnden i Göteborg) approved on the 25th March 2008 (ref: 120-08)

Study design
Double-blinded single centre randomised controlled trial

Primary study design
Interventional

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Infertility

Interventions
1. Intervention arm: Embryos for transfer will be chosen by performing a morphological evaluation of the embryos and an analysis of the culture media by NIR
2. Control arm: Embryos for transfer will be chosen solely based on morphology

The duration of the "treatment" is 30 minutes per couple. The total follow-up time is 7 weeks after embryo transfer per patient.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Number of ongoing pregnancies per randomised patient (intention to treat), based on fetal heart activity by means of ultrasound 45 days after embryo transfer.

Key secondary outcome(s))
1. Total number of positive pregnancy tests per randomised patient, 18 days after embryo test
2. Number on ongoing pregnancies per randomised patient, based on fetal heart activity by means of ultrasound 45 days after embryo transfer on day 2
3. Number on ongoing pregnancies per randomised patient, based on fetal heart activity by means of ultrasound 45 days after embryo transfer on day 5
4. Number of ongoing pregnancies per embryo randomised patient, where only those embryos reaching the threshold level of viability from the NIR analysis will be included

Completion date

01/09/2011

Eligibility

Key inclusion criteria
1. All patients seeking IVF at Fertitlity Center Scandinavia, Gothenburg, Sweden
2. Signed an informed written consent to participate in the study
3. Aged 25 - 45 years, male and female (couple entering an IVF treatment)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Previously randomised in the study
2. On the day of embryo transfer (culture day 2 or 5) the couple must have at least 2 embryos of good morphological quality (GQE)
3. Only single embryo transfer is allowed
4. Testicular biopsy patients (testicular sperm aspiration [TESA]/testicular sperm extraction [TESE])
5. Embryo transfer on day 3 or day 4

Date of first enrolment
01/06/2009

Date of final enrolment
01/09/2011

Locations

Countries of recruitment
Sweden

Study participating centre
Fertility Centre, Box 5418
Gothenburg
Sweden
40229

Sponsor information

Organisation
Molecular Biometrics (MB) LLC (USA)

Funder(s)

Funder type
Industry

Funder Name
Molecular Biometrics (MB) LLC (USA) - provided the NIR spectroscopic technology and provides some financial support through a research position held at the clinic

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2011		Yes	No
Results article	results	01/01/2012		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes