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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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 04/09/2009	**Overall study status** Completed	
Last Edited 18/04/2012	**Condition category** Pregnancy and Childbirth	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Can be found at http://www.fertilitetscentrum.se/51.html (Swedish only)

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

Secondary outcome measures
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

Overall study start date
01/06/2009

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

Age group
Adult

Sex
Both

Target number of participants
752

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)

Sponsor details
5 Topping Way
Chester
United States of America
07930

Sponsor type
Industry

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

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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