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PROMOTE: A prospective randomised trial comparing embryo development

Submission date	Recruitment status	[X] Prospectively registered
08/01/2015	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
12/01/2015	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
27/10/2022	Pregnancy and Childbirth	

Plain English summary of protocol

Background and study aims
The EmbryoScope™ is an IVF incubator with built in camera that monitors the development of embryos around the clock. It provides a safe incubator environment from conception thogh to time of transfer.
This trial examines whether an Embryoscope provides a better environment to culture embryos in when compared to a traditional MINC benchtop incubator. The Embryoscope allows the developing embryo to be imaged at regular intervals without removing them from the incubator thus providing them with a constant environment.

Who can participate?
Couples who have more than 6 healthy embryos

What does the study involve?
The embryos are randomly allocated into one of two groups. Those in group 1 are placed in the EmbryoScope™. Those in group 2 are placed in the MINC incubator. The embryos are assessed by examining their structure and form (morphology) and how this changes over time (morphokinetics). In addition to this, the metabolism of the embryos are examined by measuring the concentrations of essential nutrients in the culture medium. This is because it is thought that "quiet" embryos i.e. those who use less nutrients, are in fact more viable.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
University of Southampton (UK)

When is the study starting and how long is it expected to run for?
January 2015 to December 2015

Who is funding the study?
1. Unisense FertiliTech A/S (Denmark)
2. National Institute for Health Research (UK)

Who is the main contact?
Dr Alexandra Kermack

Contact information

Type(s)
Scientific

Contact name
Dr Alexandra Kermack

Contact details
University of Southampton
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
17907

Study information

Scientific Title
PROMOTE: A Prospective Randomised trial cOmparing embryo Metabolism and develOpmenT in the standard versus the Embryoscope incubator

Acronym
PROMOTE

Study objectives
Are embryos cultures in an Embryoscope more likely to reach blastocyst stage when compared with those cultured in a MINC benchtop incubator? The research question is being posed because the Embryoscope is an incubator which allows embryos to be observed without removing them from the culture chamber, and there is some evidence to suggest that these embryos benefit from more stable conditions.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee South Central – Berkshire, 03/11/2014, ref: 14/SC/1260

Study design
Randomised; Interventional

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Topic: Reproductive health and childbirth; Subtopic: Reproductive Health and Childb (all Subtopics); Disease: Reproductive Health & Childbirth

Interventions
1. Embryoscope: Half of the female participant's embryos will be cultured in the Embryoscope
2. MINC benchtop incubator: Half of the female participant's embryos will be cultured in the MINC benchtop incubator

Intervention Type
Procedure/Surgery

Primary outcome measure
Proportion of embryos reaching blastocyst stage in Embryoscope versus MINC benchtop incubator on day 5 after culture in the Embryoscope

Secondary outcome measures
1. A comparison of the mean morphology score of embryos from each cohort on day 5 after culture in the Embryoscope versus the MINC incubator
2. Number of embryos suitable for cryopreservation from Embryoscope versus MINC
3. Number of “usable” embryos from Embryoscope versus MINC
4. Implantation rate in relation to metabolic activity of embryo(s) transferred
5. A comparison of the amino acid profile in the conditioned media obtained from blastocysts after culture in the Embryoscope versus the MINC Incubator
6. Correlation between metabolic activity and embryo viability as assessed by morphological and morphokinetic assessment

Overall study start date

05/01/2015

Completion date
31/12/2015

Eligibility

Key inclusion criteria
1. Standard indication for IVF/ICSI treatment
2. Good understanding of written and spoken English
3. Female age under 42
4. Antral Follicle Count (AFC) of more than 15 or Anti Mullerian Hormone (AMH) of more than 10pmol/l

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
Planned Sample Size: 120; UK Sample Size: 120; Description: 60 couples but consented individually

Key exclusion criteria
1. Any medical contraindication to IVF/ICSI
2. Previous diagnosis of HIV, Hep B or Hep C
3. High risk of Ovarian Hyperstimulation Syndrome (OHSS) as assessed prior to triggering of final oocyte maturation
4. Less than 6 2PN zygotes or more than 14 2PN zygotes available for culture

Date of first enrolment
15/01/2015

Date of final enrolment
30/10/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

University of Southampton
Academic Unit of Genetic Medicine
Coxford Road
Southampton
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SO16 5YA

Sponsor information

Organisation
Southampton University Hospitals NHS Trust

Sponsor details
Cancer Care Directorate
B Level, Mailpoint WRE
Royal South Hants Hospital
Graham Road
Southampton
England
United Kingdom
SO14 0YG

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/0485axj58

Funder(s)

Funder type
Government

Funder Name
Unisense FertiliTech A/S (Denmark)

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

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		26/10/2022	27/10/2022	Yes	No
HRA research summary			28/06/2023	No	No