

# PROMOTE: A prospective randomised trial comparing embryo development

<b>Submission date</b> 08/01/2015	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 12/01/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 27/10/2022	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data

## 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 though 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 FertilTech 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  
Academic Unit of Genetic Medicine  
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Southampton  
United Kingdom  
SO16 5YA

## 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  
United Kingdom  
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?
<a href="#">Results article</a>		26/10/2022	27/10/2022	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No