

Efficacy and Cost Effectiveness of Selective Single Embryo transfer

Submission date 29/11/2005	Recruitment status Stopped	☐ Prospectively registered ☒ Protocol
Registration date 16/01/2006	Overall study status Stopped	☐ Statistical analysis plan ☐ Results
Last Edited 12/12/2012	Condition category Pregnancy and Childbirth	☐ Individual participant data ☐ Record updated in last year

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
04/S0801/80

Study information

Scientific Title
Efficacy and Cost Effectiveness of Selective Single Embryo transfer: a multi-centre randomised controlled trial

Acronym

ECoSSE

Study objectives

That single embryo transfer is as effective and as acceptable as double embryo transfer.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approval received from the Grampian Local Research Ethics Committee (ref: 04/S0801/80).

Primary study design

Interventional

Study design

Multi-centre randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Infertility

Interventions

Single-embryo transfer or double-embryo transfer.

Added 21/02/2007:

Please note that this trial has been stopped due to poor recruitment and the fact that the clinical question is less relevant as many other trials had been published since this trial was planned.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Live birth per woman.

Key secondary outcome(s)

1. Pregnancy rate per woman
2. Multiple pregnancy rate
3. Obstetric and perinatal morbidity
4. Cost effectiveness and cost utility
5. Acceptability and satisfaction

Completion date

31/12/2009

Reason abandoned (if study stopped)

1. Participant recruitment issue 2. Objectives no longer viable

Eligibility

Key inclusion criteria

1. Women aged 37 years or less
2. Undergoing In Vitro Fertilisation (IVF) or Intracytoplasmic Sperm Injection (ICSI)
3. In the first or second cycle of treatment or with a previous IVF live birth
4. Four or more good quality embryos at the time of embryo transfer

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

1. Pre-implantation genetic diagnosis
2. Assisted hatching
3. History of recurrent miscarriage (three or more)
4. Multiple IVF failure
5. Donor or recipient of gametes
6. Previous non-IVF live birth

Date of first enrolment

01/01/2005

Date of final enrolment

31/12/2009

Locations

Countries of recruitment

United Kingdom

Scotland

Study participating centre

Department of Obstetrics & Gynaecology
Aberdeen
United Kingdom
AB25 2ZD

Sponsor information

Organisation

University of Aberdeen (UK)

ROR

<https://ror.org/016476m91>

Funder(s)

Funder type

Charity

Funder Name

The Wellcome Trust (UK) (grant ref: 067469)

Funder Name

The Bertarelli Foundation (Switzerland)

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?
Protocol article	Protocol	01/09/2005		Yes	No