ISRCTN86466058 https://doi.org/10.1186/ISRCTN86466058

Efficacy and Cost Effectiveness of Selective Single Embryo transfer

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Siladitya Bhattacharya

Contact details
Department of Obstetrics & Gynaecology
University of Aberdeen
Foresterhill
Aberdeen
United Kingdom
AB25 2ZD
+44 (0)1224 553 267
s.bhattacharya@abdn.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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).

Study design
Multi-centre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
Live birth per woman.

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

Overall study start date
01/01/2005

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

Age group
Adult

Sex
Female

Target number of participants
700

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
Scotland

United Kingdom

Study participating centre
Department of Obstetrics & Gynaecology
Aberdeen
United Kingdom
AB25 2ZD

Sponsor information

Organisation
University of Aberdeen (UK)

Sponsor details
Research & Innovation
University Office
King's College
Aberdeen
Scotland
United Kingdom
AB24 3FX

Sponsor type
University/education

Website
http://www.abdn.ac.uk/R&I

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

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?
Protocol article	Protocol	01/09/2005		Yes	No