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Scottish Unexplained Infertility Trial: a randomised trial of clomiphene versus intrauterine insemination for unexplained infertility

Submission date
16/03/2005

Recruitment status
No longer recruiting

Registration date
01/09/2005

Overall study status
Completed

Last Edited
30/10/2012

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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
CZH/4/17

Study information

Scientific Title

Acronym
SUIT

Study objectives
To assess the efficacy of clomiphene citrate versus intrauterine insemination (IUI) versus no treatment using the partner's semen sample in the treatment of unexplained infertility.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Infertility

Interventions
Clomifene citrate versus intrauterine insemination versus expectant management.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Clomifene citrate

Primary outcome measure
To compare the three treatments in terms of efficacy, patient acceptability and costs.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/09/2001

Completion date
31/08/2006

Eligibility

Key inclusion criteria
570 couples with unexplained infertility. Those with infertility of less than 2 years or females aged above 38 years will be excluded.

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
570

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/09/2001

Date of final enrolment
31/08/2006

Locations

Countries of recruitment
Scotland

United Kingdom

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

Sponsor information

Organisation
Individual Sponsor (UK)

Sponsor details
Mr. Fred Stevenson-Robb
Director, Research & Innovation
University of Aberdeen
University Office
King's College
Regent Walk
Old Aberdeen
Aberdeen
United Kingdom
AB24 3FX

Sponsor type
Not defined

Funder(s)

Funder type
Government

Funder Name
Chief Scientist Office of the Scottish Executive Health Department (UK) (ref: CZH/4/17)

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	07/08/2008		Yes	No
Results article	results	01/02/2011		Yes	No