ISRCTN07823656 https://doi.org/10.1186/ISRCTN07823656

A randomised preference trial of medical versus surgical termination of pregnancy less than 14 weeks' gestation

Submission date
18/05/2005

Recruitment status
No longer recruiting

Registration date
20/05/2005

Overall study status
Completed

Last Edited
01/08/2012

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

Protocol serial number
HTA 03/11/02

Study information

Scientific Title

Acronym
TOPS

Study objectives
This trial will determine the acceptability, efficacy and cost of medical and surgical termination of pregnancy using a randomised preference design. Acceptability will be determined by the proportion of women who would choose their randomised method again (primary outcome). Information on strength of preference, as determined by willingness to pay, and experiences of the medical and surgical procedures, as determined by a rating scale and adjective checklist, will be collected from all women. A conjoint analysis and semi-structured interviews to be conducted in a separate group of non-pregnant women will help build a conceptual model of preferences that will be explored in a subgroup of randomised women. Morbidity, as assessed by unplanned surgical intervention and unplanned overnight stay or readmission, as well as the prevalence of key symptoms and psychological outcomes (anxiety, depression and the impact of the event) will be determined at 2 weeks and 3 months after the procedure. A full cost-effectiveness analysis will be undertaken.

Please note that, as of 11/05/2009, the anticipated end date has been updated from 31/07/2008 to 31/08/2008.

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

Study type(s)
Not Specified

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

Interventions
Medical termination versus surgical termination

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)

Not provided at time of registration.

Key secondary outcome(s))
Not provided at time of registration.

Completion date
31/08/2008

Eligibility

Key inclusion criteria
Women requesting and accepted for termination of pregnancy at less than 14 weeks gestation

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
Not provided at time of registration.

Date of first enrolment
01/05/2005

Date of final enrolment
31/08/2008

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
School of Surgical & Reproductive Sciences
Newcastle upon Tyne
United Kingdom
NE2 4HH

Sponsor information

Organisation
Department of Health (UK)

ROR
https://ror.org/03sbpja79

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment Programme - HTA (UK)

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?
Results article	results	01/11/2009		Yes	No
Other publications	Narrative review	17/07/2008		Yes	No