

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	☐ Prospectively registered
Registration date 20/05/2005	Overall study status Completed	☐ Protocol
Last Edited 01/08/2012	Condition category Pregnancy and Childbirth	☐ Statistical analysis plan
		☒ 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.

Primary study design

Interventional

Study design

Randomised controlled trial

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