

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

<b>Submission date</b> 18/05/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 20/05/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 01/08/2012	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Prof Steve Robson

### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

## 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

### Secondary study design

Randomised controlled trial

### Study setting(s)

Not specified

### Study type(s)

Not Specified

### Participant information sheet

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

Pregnancy

**Interventions**

Medical termination versus surgical termination

**Intervention Type**

Other

**Phase**

Not Specified

**Primary outcome measure**

Not provided at time of registration.

**Secondary outcome measures**

Not provided at time of registration.

**Overall study start date**

01/05/2005

**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

**Age group**

Adult

**Sex**

Female

**Target number of participants**

Not provided at time of registration.

**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

England

United Kingdom

## Study participating centre

**School of Surgical & Reproductive Sciences**

Newcastle upon Tyne

United Kingdom

NE2 4HH

# Sponsor information

## Organisation

Department of Health (UK)

## Sponsor details

Quarry House

Quarry Hill

Leeds

United Kingdom

LS2 7UE

Sheila.Greener@doh.gsi.gov.uk

## Sponsor type

Government

## Website

<http://www.dh.gov.uk/en/index.htm>

## ROR

<https://ror.org/03sbpja79>

# Funder(s)

## Funder type

Government

## Funder Name

NIHR Health Technology Assessment Programme - HTA (UK)

# 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?
<a href="#">Other publications</a>	Narrative review	17/07/2008		Yes	No
<a href="#">Results article</a>	results	01/11/2009		Yes	No