

A randomised trial of early ultrasound screening for fetal abnormality

| | | |
|--|---|--|
| Submission date 23/01/2004 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| | | <input type="checkbox"/> Protocol |
| Registration date 23/01/2004 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan |
| | | <input type="checkbox"/> Results |
| Last Edited 09/03/2018 | Condition category Pregnancy and Childbirth | <input type="checkbox"/> Individual participant data |
| | | <input type="checkbox"/> Record updated in last year |

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Prof Stephen Robson

Contact details

Royal Victoria Infirmary
Dept of Obstetrics & Gynaecology 4th Floor
Leazes Wing
Queen Victoria Road
Newcastle upon Tyne
United Kingdom
NE1 4LP
+44 (0)191 282 4132
s.c.robson@ncl.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

RRCC138R R6003

Study information

Scientific Title

A randomised trial of early ultrasound screening for fetal abnormality

Study objectives

This is a randomised trial to evaluate the effects on pregnancy management and outcome of adding early ultrasound screening for structural and chromosomal abnormalities to an existing antenatal screening programme (maternal serum screening at 16 weeks and ultrasound screening at 18-20 weeks). The general hypothesis is that early ultrasound screening will improve maternal psychological outcome following termination of pregnancy (TOP) for fetal abnormality.

The specific hypotheses to be tested are; Primary Addition of early ultrasound screening reduces grief, depression and distress after TOP for fetal abnormality.

Secondary Addition of early ultrasound screening

1. Does not increase maternal anxiety in those receiving false positive results, while in those receiving screen negative results it
2. Provides reassurance
3. Has beneficial effects on attitudes to the fetus and
4. Has beneficial effects on smoking.

The cost-effectiveness of introducing early ultrasound screening will also be examined.

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)

Hospital

Study type(s)

Screening

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Pregnancy and childbirth: Pregnancy

Interventions

1. Early ultrasound screening for structural and chromosomal abnormalities
2. Standard care

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

1. In women undergoing TOP
 - 1.1. Grief (Perinatal Grief scale)
 - 1.2. Depression (HAD-D scale)
 - 1.3. Distress (Impact of Events scale)
2. In women receiving screen positive results (ultrasound or serum screening):
 - 2.1. Anxiety (HAD-A scale and State-Trait Anxiety scale)
3. In women receiving screen negative results:
 - 3.1. Anxiety (HAD-A scale)
 - 3.2. Maternal-Fetal Attachment Scale
 - 3.3. Smoking status
4. Costs (patient and NHS) and cost utilities
5. Prevalence of congenital abnormalities (detected up to one month of age)
6. Total and late TOP for fetal abnormality
7. Perinatal mortality

Secondary outcome measures

Not provided at time of registration

Overall study start date

10/01/2000

Completion date

10/01/2003

Eligibility

Key inclusion criteria

15000 women (7500 in each arm) - estimate ~50 women undergoing TOP in each arm. 225 women with false positive results and 225 screen negative women.

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

15000

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

10/01/2000

Date of final enrolment

10/01/2003

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre**Royal Victoria Infirmary**

Newcastle upon Tyne

United Kingdom

NE1 4LP

Sponsor information**Organisation**

NHS R&D Regional Programme Register - Department of Health (UK)

Sponsor details

The Department of Health

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL

+44 (0)20 7307 2622

dhmail@doh.gsi.org.uk

Sponsor type

Government

Website

<http://www.doh.gov.uk>

Funder(s)

Funder type

Not defined

Funder Name

NHS Executive Northern and Yorkshire (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