ISRCTN37543746 https://doi.org/10.1186/ISRCTN37543746

A randomised trial of early ultrasound screening for fetal abnormality

Submission date 23/01/2004	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 23/01/2004	**Overall study status** Completed	
Last Edited 09/03/2018	**Condition category** Pregnancy and Childbirth	

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