

A randomised trial of early ultrasound screening for fetal abnormality

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		<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

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Additional identifiers

Protocol serial number
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

Study type(s)

Screening

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(s)

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

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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

United Kingdom

England

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)

Funder(s)

Funder type

Not defined

Funder Name

NHS Executive Northern and Yorkshire (UK)

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Not provided at time of registration