

Amniocentesis Results: Investigation of Anxiety

| | | |
|--|---|--|
| Submission date 17/10/2002 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| Registration date 17/10/2002 | Overall study status Completed | <input type="checkbox"/> Protocol |
| Last Edited 08/08/2019 | Condition category 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 Jenny Hewison

Contact details
Academic Department of Psychiatry and Behavioural Sciences
University of Leeds
15 Hyde Terrace
Leeds
United Kingdom
LS2 9LT
+44 (0)113 343 1894
j.hewison@leeds.ac.uk

Additional identifiers

Protocol serial number
HTA 99/48/04

Study information

Scientific Title
Amniocentesis Results: Investigation of Anxiety

Acronym
ARIA

Study objectives

There is evidence both that being able to predict stressful events, and having information which normalises the content and timing of worries about such events, reduces anxiety. This provides scope for interventions designed to minimise anxiety while waiting for test results.

Phase one:

1. To identify patterns of anxiety and the factors that contribute to this.
2. To develop an appropriate intervention for phase two, the RCT.
3. To obtain information about the patterns of anxiety which will inform the outcome measures and the timing of measurement in the RCT.

Phase two - to test the following hypotheses:

1. That giving amniocentesis results out on a fixed date with an undertaking not to phone earlier even if possible, alters maternal anxiety during the waiting period, compared with a policy of phoning as soon as possible.
2. Providing parents with a "debriefing" leaflet describing the normal pattern of worry during the waiting period, reduces anxiety.

Please note that, as of 15 January 2008, the start and end dates of this trial have been updated from 1 January 2001 and 31 December 2003 to 1 September 2001 and 31 March 2005, respectively.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

2 X 2 factorial design randomised controlled trial

Primary study design

Interventional

Study type(s)

Not Specified

Health condition(s) or problem(s) studied

Pregnancy

Interventions

Phase one: an observational cohort study (n=30) using anxiety diaries and qualitative interviews. Phase two: a 2 X 2 factorial design randomised controlled trial. Participants will be randomised immediately after amniocentesis to "phone result when available" or "issue result on a fixed date" and to "leaflet" or "no leaflet". The trial will use independent telephone randomisation, stratified by centre and maternal age (<35, >=35years). Setting: seven amniocentesis clinics = Leeds General Infirmary and St James's, Airedale, Harrogate, York, Hull Maternity Hospital and Castle Hill.

The aim is to investigate how two interventions, firstly, the issue of a standard culture result on

a fixed date (18 days after amniocentesis) or variable date, secondly, how the implementation of a new cytogenetic technique, Fluorescent In-situ Hybridisation (FISH), affect maternal anxiety levels.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

We will measure anxiety daily using the short Spielberger state measure with regular phone reminders The primary outcomes will be total anxiety in the first 24 hours after the test, over the last 24 hours before the result is issued, and the peak level of anxiety reached. Within 24 hours of issuing the results, parents will be asked to recall and score their anxiety over the waiting period. This will provide validation of the prospectively collected scores. We will not conduct any economic analysis because the costs of different modes of issuing results will be similar and the leaflets will be cheap. We will recommend that the method, which minimises anxiety, be used.

Key secondary outcome(s)

Not provided at time of registration

Completion date

31/03/2005

Eligibility**Key inclusion criteria**

Pregnant women who are having an amniocentesis for indications such as maternal age, triple test risk or the presence of a soft marker for Downs Syndrome

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Total final enrolment

226

Key exclusion criteria

Women with a major structural abnormality on scan. Women who miscarry before the karyotype result is obtained (<1%) or whose result indicates aneuploidy (1 in 70) will be excluded from the primary analysis.

Date of first enrolment

01/09/2001

Date of final enrolment

31/03/2005

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Academic Department of Psychiatry and Behavioural Sciences

Leeds

United Kingdom

LS2 9LT

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 | 01/12/2006 | | Yes | No |
| Results article | results | 01/04/2007 | 08/08/2019 | Yes | No |
| Study website | Study website | 11/11/2025 | 11/11/2025 | No | Yes |