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Amniocentesis Results: Investigation of Anxiety

Submission date	Recruitment status	[_] Prospectively registered
17/10/2002	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
17/10/2002	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
08/08/2019	Pregnancy and Childbirth	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.leeds.ac.uk/medicine/psychiatry/research/aria.htm

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

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
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 measure
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.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/09/2001

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

Age group
Adult

Sex
Female

Target number of participants
226

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
England

United Kingdom

Study participating centre
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Sponsor information

Organisation
Department of Health (UK)

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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?
Results article	results	01/12/2006		Yes	No
Results article	results	01/04/2007	08/08/2019	Yes	No