

Amniocentesis results: investigation of anxiety. The ARIA trial

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Executive summary

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Executive summary

Background

Many pregnant women experience anxiety while waiting for the results of diagnostic tests. Policies and practices intended to reduce this anxiety require evaluation.

Objectives

The Amniocentesis Results: Investigation of Anxiety (ARIA) trial tested two hypotheses:

- Giving amniocentesis results out on a fixed date alters maternal anxiety during the waiting period, compared with a policy of telling parents that the result will be issued 'when available' (i.e. variable date).
- Issuing early results from a rapid molecular test alters maternal anxiety during the waiting period, compared with not receiving any results prior to the karyotype.

The effects of the two interventions on anxiety 1 month after receiving karyotype results were also examined.

Design

A multi-centre, randomised, controlled, open fixed sample, 2 × 2 factorial design trial, with equal randomisation.

Setting

Twelve hospitals in England offering amniocentesis as a diagnostic test for Down's syndrome.

Participants

A total of 226 women who had had an amniocentesis were randomised between June 2002 and July 2004. Eight women with abnormal results or test failure were excluded post-randomisation.

Interventions

Two interventions were used in the trial:

- issuing karyotype results on a prespecified fixed date, rather than issuing them as soon as they became available
- issuing karyotype results alone, or subsequent to issuing results from a rapid molecular test for the most common chromosomal abnormalities.

Main outcome measures

Three outcome measures were considered:

- average anxiety during the waiting period, calculated using daily scores from the short version of the Spielberger State–Trait Anxiety Inventory (STAI)
- recalled anxiety, measured 1 month after receiving karyotype results, using a rating scale
- anxiety at the 1-month follow-up, measured using the short-form STAI.

Results

No evidence was found that giving out karyotype results on a fixed or on a variable date altered maternal anxiety during the waiting period. However, the analysis only had sufficient power to detect a moderate to large effect. Issuing early results from a partial but rapid test reduced maternal anxiety by a clinically significant amount during the waiting period, compared with receiving only the full karyotype results. This was a moderate to large effect.

Additionally, group differences in recalled anxiety reflected fairly closely the differences in anxiety that women had experienced while waiting for results. One month after receiving normal karyotype results, anxiety was low in all groups, but women who had been given rapid test results were more anxious than those who had not. This was a small to moderate effect.

Conclusions

Implications for healthcare

Since there are no clear advantages in anxiety terms of issuing karyotype results as soon as they become available, or on a fixed date, women could be given a choice between them.

Rapid testing was a beneficial addition to karyotyping, at least in the short term. This does not necessarily imply that early results would be preferred to comprehensive ones if women had to choose between them.

Recommendations for research

Further research could be considered for the following:

- more qualitative studies into the causes, characteristics and consequences of anxiety associated with prenatal testing

- the effects of different testing regimes on short and longer-term anxiety, on the preferences of women, and on the relationship between anxiety and preference
- consideration of the ways in which information might be used to minimise anxiety in different testing regimes
- policy implications of incorporating individual preferences for different testing regimes into prenatal testing programmes.

Publication

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NHS R&D HTA Programme

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The research reported in this monograph was commissioned by the HTA Programme as project number 99/48/04. The contractual start date was in September 2001. The draft report began editorial review in July 2005 and was accepted for publication in February 2006. As the funder, by devising a commissioning brief, the HTA Programme specified the research question and study design. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the referees for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

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