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A randomised controlled trial of different approaches to universal antenatal Human Immunodeficiency Virus (HIV) testing: acceptability, costs and benefits

Submission date
25/04/2003

Recruitment status
No longer recruiting

Registration date
25/04/2003

Overall study status
Completed

Last Edited
08/11/2022

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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
HTA 93/24/11

Study information

Scientific Title
A randomised controlled trial of different approaches to universal antenatal Human Immunodeficiency Virus (HIV) testing: acceptability, costs and benefits

Study objectives
With increasing optimism about the benefits of antenatal HIV testing, particularly in terms of measures that greatly reduce the risk of infection to the baby, there is a demand for effective, acceptable testing programmes and appropriate patient information. This randomised controlled trial (RCT) was designed to compare different ways of offering testing to all pregnant women, with the aim of acquiring information about what predicts uptake and how women respond to the offer of testing, in order to define the optimal approach.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration.

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Not Specified

Health condition(s) or problem(s) studied
Infection and infestations: HIV/Acquired Immunodeficiency Syndrome (AIDS); Pregnancy and childbirth: Pregnancy

Interventions
The setting was a hospital antenatal clinic covering the majority of the population of Edinburgh City. The target group was all pregnant women booking at the clinic over 10 months. The design was an RCT involving four combinations of written and verbal communication, followed by the direct offer of an HIV test with written consent required for testing.
Women were sent either a specific leaflet about HIV testing in pregnancy or a leaflet containing information about HIV testing amongst information on the other antenatal blood tests. At the clinic, a core group of ten trained midwives offered the test, following either minimal or comprehensive pre-test discussion protocols printed on cards. The control group received no information and no direct offer of a test, although testing was available on request (the pre-trial situation).

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)

The main outcome measures were uptake of HIV testing, knowledge of HIV and other antenatal tests, satisfaction with the consultation, anxiety, attitudes towards pregnancy and perceived benefits of testing. Opinions about testing during pregnancy were also sought using both quantitative and qualitative measures. Midwives' knowledge and attitudes were assessed to investigate their effect on women's uptake of testing.

Key secondary outcome(s)
Not provided at time of registration.

Completion date
31/07/1998

Eligibility

Key inclusion criteria
Participants were 3024 pregnant women, of whom 2704 (89%) completed a questionnaire which determined acceptability of testing, at their booking appointment. A sub-sample of the participants (n = 788) also completed a questionnaire at their 32-week appointment.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
Not provided at time of registration.

Date of first enrolment
01/04/1995

Date of final enrolment
31/07/1998

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre

Dept of Obstetrics and Gynaecology
Edinburgh
United Kingdom
EH3 9EW

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
Not provided at time of registration

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	HTA monograph	01/04/1999		Yes	No