ISRCTN40371436 https://doi.org/10.1186/ISRCTN40371436

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

Contact name
Dr Frank Johnstone

Contact details
Dept of Obstetrics and Gynaecology
University of Edinburgh
37 Chalmers Street
Edinburgh
United Kingdom
EH3 9EW
+44 (0)131 229 2575 x2315
fdj@srv1.med.ed.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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.

Study 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
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 measure
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.

Secondary outcome measures
Not provided at time of registration.

Overall study start date
01/04/1995

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

Age group
Adult

Sex
Female

Target number of participants
3024

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
Scotland

United Kingdom

Study participating centre
Dept of Obstetrics and Gynaecology
Edinburgh
United Kingdom
EH3 9EW

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Quarry House
Quarry Hill
Leeds
United Kingdom
LS2 7UE
+44 (0)1132 545 843
Sheila.Greener@doh.gsi.gov.uk

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
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