ISRCTN63422923 https://doi.org/10.1186/ISRCTN63422923

Active versus expectant management of third stage of labour: the Hinchingbrooke randomised controlled trial

Submission date
23/01/2004

Recruitment status
No longer recruiting

Registration date
23/01/2004

Overall study status
Completed

Last Edited
13/10/2014

Condition category
Pregnancy and Childbirth

[_] 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 Diana Elbourne

Contact details
Medical Statistics Unit
London School of Hygiene and Tropical Medicine
London
United Kingdom
WC1E 7HT

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Study objectives
This study tested the hypothesis that active management of the third stage of labour lowers the rates of primary postpartum haemorrhage and longer-term consequences compared with expectant management, in a setting where both managements are commonly practised, and that this effect is not mediated by maternal posture.

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)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Pregnancy and childbirth: Childbirth

Interventions
1. Active management of the third stage (prophylactic oxytocic within 2 minutes of baby's birth, immediate cutting and clamping of the cord, delivery of placenta by controlled cord traction or maternal effort)
2. Expectant management (no prophylactic oxytocic, no cord clamping until pulsation ceased, delivery of placenta by maternal effort. Women were also randomly assigned upright or supine position.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Rate of postpartum haemorrhage

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/06/1993

Completion date
01/12/1995

Eligibility

Key inclusion criteria
Women judged to be at low risk of primary postpartum haemorrhage (PPH) (blood loss greater than 500 ml)

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
1512

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/06/1993

Date of final enrolment
01/12/1995

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Medical Statistics Unit
London
United Kingdom
WC1E 7HT

Sponsor information

Organisation
NHS R&D Regional Programme Register - Department of Health (UK)

Sponsor details
The Department of Health
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
NHS Executive Eastern (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	07/03/1998		Yes	No