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Effect of a labour electronic fetal monitoring admission test on operative delivery in low-risk women: a randomised controlled trial

Submission date
12/09/2003

Recruitment status
No longer recruiting

Registration date
12/09/2003

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
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0245109928

Study information

Scientific Title

Study objectives
What is the relationship between the labour Electronic Fetal Monitoring (EFM) admission test and obstetric intervention for low-risk mothers?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Mid and South Bucks Local Research Ethics Committee, approved on 30/12/1999 (ref: NC947), last amendment approved on 07/09/2005. Following a pilot study, approval for the change to the target number of participants obtained on 16/09/2003

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Pregnancy and Childbirth: Labour electronic fetal monitoring (EFM)

Interventions
This study will be of experimental design and will consist of a randomised, controlled trial. The trial is designed to answer the main question.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Primary outcome measure amended as of 05/03/2008:
Rate of operative delivery.

Primary outcome measures provided at time of registration:
Four indicators of obstetric intervention:
1. Rate of operative delivery
2. Rate of augmentation using an oxytocin infusion
3. Rate of episiotomy in normal deliveries
4. Rate of siting of an intravenous infusion

Secondary outcome measures
Secondary outcome measures added as of 05/03/2008:
1. Rate of augmentation using an oxytocin infusion
2. Rate of siting of an intravenous infusion

Overall study start date
01/11/2002

Completion date
10/03/2006

Eligibility

Key inclusion criteria
Inclusion criteria amended as of 03/09/2007:
Labouring women who attend the delivery suite involved in the study, who upon admission to hospital are considered to be of low risk of fetal or maternal complications. Low risk being defined as mothers who lack all of the criteria for exclusion. Around 1200 clients fulfilling this criteria were admitted to the unit to be studied in the period Jun 98-Jun 99.

Treatment arm (admission test) - 750 women
Control arm (no admission test) - 750 women

Inclusion criteria provided at time of registration:
Labouring women who attend the delivery suite involved in the study, who upon admission to hospital are considered to be of low risk of fetal or maternal complications. Low risk being defined as mothers who lack all of the criteria for exclusion. Around 1200 clients fulfilling this criteria were admitted to the unit to be studied in the period Jun 98-Jun 99.

Treatment arm (admission test) - 375 women
Control arm (no admission test) - 375 women

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
Target number amended as of 03/09/2007: 1500. Target number provided at time of registration: 750.

Key exclusion criteria
Added as of 07/03/2008:
Any woman having any of the following indicators of high risk upon admission in labour were excluded from the study:
1. Any major maternal medical complication e.g., diabetes, or essential hypertension
2. Previous caesarean section
3. Pre-term labour (less than 37 completed weeks)
4. Multiple pregnancy
5. Prolonged pregnancy (over 42 completed weeks)
6. Prolonged membrane rupture (over 24 hours)
7. Induction of labour
8. Meconium stained liquor
9. Maternal pyrexia
10. Rhesus sensitisation
11. Polyhydramnios
12. Oligohydramnios
13. Pre-eclampsia or blood pressure over 140/90 mmHg
14. Abnormal presentation or lie (e.g., breech or transverse)
15. High head (5/5ths palpable per abdomen)
16. Antepartum or intrapartum haemorrhage
17. Known or suspected intrauterine growth retardation
18. Any known or suspected fetal medical complication
19. Abnormal doppler artery velocimetry
20. Known fetal malformation
21. Poor obstetric history (e.g., history of stillbirth)
22. Unbooked cases

Date of first enrolment
01/11/2002

Date of final enrolment
10/03/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Obstetrics and Gynaecology Department
Aylesbury
United Kingdom
HP21 8AL

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

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

Funder(s)

Funder type
Government

Funder Name
Stoke Mandeville Hospital NHS Trust (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	01/03/2008		Yes	No