

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	<input type="checkbox"/> Prospectively registered
Registration date 12/09/2003	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 13/10/2014	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

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

Primary study design

Intentional

Study design

Randomised controlled trial

Study type(s)

Not Specified

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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

United Kingdom

England

Study participating centre

Obstetrics and Gynaecology Department

Aylesbury

United Kingdom

HP21 8AL

Sponsor information

Organisation

Department of Health (UK)

Funder(s)

Funder type

Government

Funder Name

Stoke Mandeville Hospital NHS Trust (UK)

Results and Publications

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