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

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>	
12/09/2003	No longer recruiting	☐ Protocol	
Registration date	Overall study status	Statistical analysis plan	
12/09/2003	Completed	[X] Results	
Last Edited	Condition category	[] Individual participant data	
13/10/2014	Pregnancy and Childbirth		

# Plain English summary of protocol

Not provided at time of registration

# Contact information

#### Type(s)

Scientific

#### Contact name

Mrs Katie Mitchell

#### Contact details

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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

#### Study design

Randomised controlled trial

#### Primary study design

Interventional

#### 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

#### 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