# Randomised controlled trial of the clinical impact of an intelligent decision making support tool for labour management using the cardiotocogram

Recruitment status	<ul><li>Prospectively registered</li></ul>
No longer recruiting	Protocol
Overall study status	Statistical analysis plan
Completed	Results
Condition category	Individual participant data
Pregnancy and Childbirth	<ul><li>Record updated in last year</li></ul>
	Overall study status Completed Condition category

#### Plain English summary of protocol

Not provided at time of registration

## Contact information

## Type(s)

Scientific

#### Contact name

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#### Contact details

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# Additional identifiers

# Protocol serial number

G9721800

# Study information

#### Scientific Title

Randomised controlled trial of the clinical impact of an intelligent decision making support tool for labour management using the cardiotocogram

#### **Study objectives**

To determine whether an intelligent support system can improve outcomes for mother and baby for current foetal monitoring by reducing human error.

#### 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

#### Study type(s)

**Not Specified** 

#### Health condition(s) or problem(s) studied

Obstetrics and gynaecology

#### Interventions

EFM with and without decision support

Delivery - operative (Caesarean section or forceps) or spontaneous

## Added 19/08/09:

Follow-up: One month in first instance. Longer term follow-up will almost certainly occur as part of a paediatric developmental study.

#### Intervention Type

Other

#### Phase

**Not Specified** 

#### Primary outcome(s)

Operative delivery rates for mother. Cord blood gas analysis, admissions to NICU, neonatal encephalopathy and perinatal mortality rates for baby.

#### Key secondary outcome(s))

Not provided at time of registration

#### Completion date

# **Eligibility**

#### Key inclusion criteria

All consented pregnancies after 34 weeks gestation with no gross foetal anomaly undergoing electronic foetal monitoring (EFM) in labour

#### Participant type(s)

**Patient** 

#### Healthy volunteers allowed

No

#### Age group

Adult

#### Sex

**Female** 

#### Key exclusion criteria

Not provided at time of registration

#### Date of first enrolment

01/06/1999

#### Date of final enrolment

31/05/2004

# Locations

#### Countries of recruitment

**United Kingdom** 

England

## Study participating centre Perinatal Research Group

Plymouth United Kingdom PL6 8DH

# **Sponsor information**

## Organisation

# Funder(s)

## Funder type

Research council

#### **Funder Name**

Medical Research Council (MRC) (UK)

#### Alternative Name(s)

Medical Research Council (United Kingdom), UK Medical Research Council, MRC

#### Funding Body Type

Government organisation

#### **Funding Body Subtype**

National government

#### Location

United Kingdom

# **Results and Publications**

Individual participant data (IPD) sharing plan

# IPD sharing plan summary

Not provided at time of registration