

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

Submission date 25/10/2000	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 25/10/2000	Overall study status Completed	☐ Protocol
Last Edited 28/02/2018	Condition category Pregnancy and Childbirth	☐ Statistical analysis plan
		☐ Results
		☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Prof Keith Greene

Contact details

Perinatal Research Group
Postgraduate Medical School
University of Plymouth
Maternity Unit
Derriford Hospital
Plymouth
United Kingdom
PL6 8DH
+44 1752 763631
k.greene@plymouth.ac.uk

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

31/05/2004

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

Medical Research Council (MRC) (UK)

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, Medical Research Committee and Advisory 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