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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

Registration date
25/10/2000

Overall study status
Completed

Last Edited
28/02/2018

Condition category
Pregnancy and Childbirth

[ ] Prospectively registered
[ ] Protocol
[ ] 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