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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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

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

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/06/1999

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

Age group
Adult

Sex
Female

Target number of participants
Corrected 19/08/09: data collection on all deliveries (30,000 - 35,000) occurring in the 6 units during the study of the 15,000 monitored in the RCT.

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

England

United Kingdom

Study participating centre
Perinatal Research Group
Plymouth
United Kingdom
PL6 8DH

Sponsor information

Organisation
Medical Research Council (MRC) (UK)

Sponsor details
20 Park Crescent
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Sponsor type
Research council

Website
http://www.mrc.ac.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, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration