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Evaluation of a computer system that alerts heathcare professionals to changes in foetal monitoring signals acquired during labour

Submission date 02/12/2008	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 26/01/2009	**Overall study status** Completed	
Last Edited 08/12/2016	**Condition category** Pregnancy and Childbirth	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Diogo Ayres-de-Campos

Contact details
Departamento de Ginecologia e Obstetrícia
Faculdade de Medicina do Porto
Porto
Portugal
4200-319
+351 96 670 7112
sisporto@med.up.pt

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A randomised clinical trial of intrapartum foetal monitoring with computer analysis and alerts versus previously available monitoring

Acronym
EFM-ALERT

Study objectives
Use of a system for computer analysis of intrapartum foetal monitoring signals, with real-time alerts for healthcare professionals, will reduce the number of foetuses born with metabolic acidosis, when compared with conventional monitoring.

Ethics approval required
Old ethics approval format

Ethics approval(s)
To be submitted as of 02/12/2008.

Study design
Randomised controlled open multi-centre trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Intrapartum foetal hypoxia

Interventions
Continuous foetal monitoring during labour with computer analysis by the Omniview-SisPorto 3.5 system vs continuous intrapartum monitoring as previously performed.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Incidence of foetal metabolic acidosis, defined as newborn umbilical artery pH <7.05 and BDecf >12 mmol/L.

Secondary outcome measures
1. Overall rates of caesarean section and caesarean section for non-reassuring foetal state
2. Overall rates of instrumental vaginal delivery and instrumental vaginal delivery for non-reassuring foetal state
3. Foetal blood sampling rates
4. Incidence of 5-minute Apgar score <7
5. Need for neonatal intensive care unit admission
6. Incidence of moderate and severe neonatal encephalopathy with a hypoxic marker
7. Perinatal death
8. Rate of delayed interventions (interval between red alerts [intervention arm]/offline analysis [control arm] and delivery in metabolic acidosis cases)
8. Tracing quality and signal loss

Overall study start date
01/04/2009

Completion date
01/04/2011

Eligibility

Key inclusion criteria
1. Pregnant women, aged more than 16 years
2. Able to provide written informed consent
3. Singleton pregnancy
4. Gestation of 36 or more completed weeks
5. Cephalic presentation
6. No known major foetal malformations
7. In active labour but not in active second stage
8. No known contraindication to vaginal delivery
9. Clinical decision made to perform continuous cardiotocography (CTG) monitoring

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
8,000

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/04/2009

Date of final enrolment
01/04/2011

Locations

Countries of recruitment
Portugal

United Kingdom

Study participating centre
Departamento de Ginecologia e Obstetrícia
Porto
Portugal
4200-319

Sponsor information

Organisation
University of Porto (Universidade do Porto) (Portugal)

Sponsor details
Faculdade de Medicina do Porto
Alameda Hernani Monteiro
Porto
Portugal
4200-319

Sponsor type
University/education

Website
http://sigarra.up.pt/fmup

ROR
https://ror.org/043pwc612

Funder(s)

Funder type
Research organisation

Funder Name
Institute of Biomedical Engineering (Instituto de Engenharia Biomédica) (INEB) (Portugal)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	28/10/2010		Yes	No
Results article	results	01/01/2017		Yes	No