

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

<b>Submission date</b> 02/12/2008	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
<b>Registration date</b> 26/01/2009	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Protocol
<b>Last Edited</b> 08/12/2016	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**Protocol serial number**  
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 fetuses 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

**Study type(s)**

Prevention

**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(s)**

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

**Key secondary outcome(s)**

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

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

Female

**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**

United Kingdom

Portugal

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

## Sponsor information

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

**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

### 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?
<a href="#">Results article</a>	results	01/01/2017		Yes	No
<a href="#">Protocol article</a>	protocol	28/10/2010		Yes	No