

A randomised controlled trial comparing the effect of ADmission Cardiotocography versus intermittent Auscultation of the foetal heart Rate on low-risk women on admission to labour ward showing signs of possible labour

Submission date 20/02/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 25/03/2008	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 11/05/2015	Condition category Pregnancy and Childbirth	<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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

RP/2006/55

Study information

Scientific Title

Foetal cardiotocography versus intermittent auscultation during labour ward admission: a randomised controlled trial and qualitative follow-up

Acronym

ADCAR

Study objectives

The admission cardiotocograph (ACTG), was introduced as a screening test to try and identify foetuses at greater risk of intrapartum asphyxia that might benefit from continuous electronic foetal monitoring (EFM) during labour. Contrary to recommendations that it should not be used for low-risk women (Royal College of Obstetricians and Gynaecologists [RCOG] 2001), an Irish survey found that routine ACTGs were done in 96% of all maternity units in the Republic of Ireland (Devane, Lalor & Bonner 2007). There have been repeated calls for a thorough evaluation of the ACTG through adequately powered randomised trials. The ADCAR trial is designed to provide this evaluation.

Null Hypothesis:

There is no significant difference between admission cardiotocography (ACTG) and intermittent auscultation (IA) of the foetal heart, in low risk women on admission to the labour ward or labour assessment room in:

1. Caesarean section
2. Obstetric intervention, and
3. Neonatal morbidity

This trial will also explore women's experience of foetal monitoring modalities.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Regional Ethics Committee - Health Services Executive, North Eastern Region (Ireland), July 2007
2. Faculty of Health Sciences, Trinity College Dublin, Research Ethics Committee, November 2007
3. Coombe Women and Infant's University Hospital, Dublin, Research Ethics Committee, February 2008

Study design

Multicentre two-group randomised trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Screening

Participant information sheet

Not yet available in web format as of 21/02/2008, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Intrapartum asphyxia

Interventions

1. Control: 20 minute CTG on admission to labour ward/assessment room with signs of labour
2. Intervention: intermittent auscultation of the foetal heart, on admission to the labour ward /assessment room with signs of labour, using a Pinard stethoscope or a Doppler ultrasound device

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Incidence of caesarean section, measured at or immediately after birth.

Secondary outcome measures

1. Obstetric intervention to include:
 - 1.1. Use of continuous EFM
 - 1.2. Use of foetal blood sampling
 - 1.3. Augmentation of labour with oxytocin
 - 1.4. Augmentation of labour with artificial rupture of membranes (ARM)
 - 1.5. Artificial rupture of membranes
 - 1.6. Labour length
 - 1.7. Epidural analgesia
 - 1.8. Episiotomy
 - 1.9. Opiate analgesia
 - 1.10. Perineal trauma requiring repair (excluding episiotomy)
 - 1.11. Estimated blood loss
 - 1.12. Mode of birth
2. Neonatal morbidity to include:
 - 2.1. Metabolic acidosis (defined as an umbilical artery blood pH less than 7.05, and a base deficit in the extracellular fluid compartment (BD) of greater than 12.0 mmol/l)
 - 2.2. Hypoxic ischaemic encephalopathy (HIE)
 - 2.3. Seizures
 - 2.4. Use of anticonvulsants
 - 2.5. Hypotonia

- 2.6. Apgar scores at one and five minutes
- 2.7. Admission to the Neonatal Intensive Care Unit (NICU)
- 2.8. Length of stay in NICU (in days)
- 2.9. Length of neonatal ventilator days
- 2.10. Neonatal death
- 2.11. Stillbirth
- 2.12. Intracranial haemorrhage
- 2.13. Meconium aspiration
- 2.14. Renal failure
- 2.15. Neonatal resuscitation
- 3. Women's experience of foetal monitoring modalities

All outcomes will be measured at or immediately after birth except for the qualitative interviews which will be carried out 6 - 8 weeks post birth.

Overall study start date

10/03/2008

Completion date

10/06/2010

Eligibility

Key inclusion criteria

- 1. Women between 37+0 and 40+6 completed weeks of pregnancy
- 2. Absence of antenatal, maternal and foetal risk factors to the development of neonatal encephalopathy, cerebral palsy or perinatal death as per RCOG, which warrant EFM
- 3. Greater than or equal to 18 years
- 4. Ability to understand study information and willingness to give written, informed consent
- 5. Women participating in interviews must be able to converse in English

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Female

Target number of participants

5,776 (2,888 per group)

Key exclusion criteria

Any criteria that does not meet the inclusion criteria.

Date of first enrolment

10/03/2008

Date of final enrolment

10/06/2010

Locations

Countries of recruitment

Ireland

Study participating centre

National University of Ireland

Galway

Ireland

-

Sponsor information

Organisation

Health Research Board (HRB) (Ireland)

Sponsor details

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Dublin

Ireland

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hrb@hrb.ie

Sponsor type

Government

Website

<http://www.hrb.ie/>

ROR

<https://ror.org/003hb2249>

Funder(s)

Funder type

Government

Funder Name

Health Research Board (HRB) (Ireland) (ref: RP/2006/55)

Alternative Name(s)

HRB

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

Ireland

Funder Name

Department of Health and Children (Ireland)

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?
Results article	recruitment rates results	10/05/2015		Yes	No