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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

Registration date
25/03/2008

Overall study status
Completed

Last Edited
11/05/2015

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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 to18 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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Sponsor type
Government

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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