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Early External Cephalic Version (ECV) 2 trial

Submission date
19/04/2004

Recruitment status
No longer recruiting

Registration date
22/04/2005

Overall study status
Completed

Last Edited
19/06/2015

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

Study website
http://www.utoronto.ca/cmicr/eecv2/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00141687

Secondary identifying numbers

MCT-65630

Study information

Scientific Title
Early External Cephalic Version (ECV) 2 trial

Acronym
EECV2

Study objectives
1. For women with a foetus in breech presentation, does early External Cephalic Version (ECV) (at 34^0/7 - 35^6/7 weeks) versus delayed ECV (not before 37^0/7 weeks) increase or decrease the likelihood of Caesarean Section (CS)?
2. Is the risk of preterm birth (less than 37^0/7 weeks) lower or higher with early versus delayed ECV?

Protocol can be found at: http://sunnybrook.ca/uploads/sri_cmicr_eecv2_protocol_en.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. The University of British Columbia Clinical Research Ethics Board, 18/08/2004, ref. no.: C04-0348, amendment 06/10/2004
2. Research Ethics Board of Hamilton Health Sciences Research Ethics Board, 20/03/2007, ref: 07-122

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Prevention

Participant information sheet
EECV2 trial information for Parents and Families available on http://www.utoronto.ca/cmicr/eecv2/pat/index.htm

Health condition(s) or problem(s) studied
Pregnancies with a foetus in breech presentation

Interventions
Women will be randomised to have either an early ECV at 34 - 35 weeks gestation, or a delayed ECV at or after 37 weeks gestation

On 01/01/2007 the sponsor changed from the Canadian Institutes of Health Research (CIHR) to the current sponsor, the McMaster University Medical Centre (see below).

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Rate of CS.

Outcomes will be measured at two planned interim analyses:
1. After 500 participants were recruited (analysis complete 02/2007)
2. After 900 participants were recruited (analysis expected to be complete 01/2008)
3. After the full sample of 1460 participants have been recruited

Secondary outcome measures
1. Rate of preterm birth
2. Other outcomes include admission to neonatal intensive care unit more than or equal to 24 hours, perinatal or neonatal mortality or serious neonatal morbidity, serious foetal complications, maternal death or serious maternal morbidity, non-cephalic presentation at birth, women's views, and health care costs

Outcomes will be measured at two planned interim analyses:
1. After 500 participants were recruited (analysis complete 02/2007)
2. After 900 participants were recruited (analysis expected to be complete 01/2008)
3. After the full sample of 1460 participants have been recruited

Overall study start date
01/12/2004

Completion date
31/12/2008

Eligibility

Key inclusion criteria
1. Women with any breech presentation, aged 18 - 49 years old
2. A live singleton foetus
3. Gestational age of 33^0/7 - 35^6/7 weeks

Participant type(s)
Patient

Age group

Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
1460 women (730 per group) are required. Recruitment complete as of July 2008.

Key exclusion criteria
1. Any contraindication to ECV
2. Previous participation in the EECV2 Trial
3. Any contraindication to early ECV
4. Women who wish a vaginal delivery if the foetus remains breech
5. Any contraindication to labour or vaginal birth
6. Women who wish to deliver by Caesarean Section (CS) if the foetus turns to cephalic
7. Women at increased risk of unstable lie

Please note that the following exclusion criteria was removed from this list on 06/11/2007:
8. Women who plan to move to a non-trial centre prior to delivery

Date of first enrolment
01/12/2004

Date of final enrolment
01/07/2008

Locations

Countries of recruitment
Argentina

Australia

Brazil

Canada

Chile

Egypt

Germany

Hungary

Ireland

Israel

Jordan

Netherlands

Poland

United States of America

Study participating centre
McMaster University
Hamilton
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Sponsor information

Organisation
McMaster University Medical Centre (Canada)

Sponsor details
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05jyrng31

Funder(s)

Funder type
Research organisation

Funder Name

Canadian Institutes of Health Research (CIHR) (Canada), ref: MCT-65630

Alternative Name(s)
Instituts de Recherche en Santé du Canada, Canadian Institutes of Health Research (CIHR), CIHR_IRSC, Canadian Institutes of Health Research | Ottawa ON, CIHR, IRSC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Canada

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	results	01/04/2011		Yes	No
Results article	results	26/09/2014		Yes	No