

Early External Cephalic Version (ECV) 2 trial

Submission date 19/04/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 22/04/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 19/06/2015	Condition category 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

ClinicalTrials.gov (NCT)
NCT00141687

Protocol serial number
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

Study type(s)

Prevention

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(s)

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

Key secondary outcome(s))

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

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 33⁰/7 - 35⁶/7 weeks

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Female

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

Canada

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Sponsor information

Organisation

McMaster University Medical Centre (Canada)

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 - Welcome to the Canadian Institutes of Health Research, CIHR, IRSC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Canada

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

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

Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes