

# Early External Cephalic Version (ECV) 2 trial

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

## Study website

<http://www.utoronto.ca/cmcr/eev2/>

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

NCT00141687

Secondary identifying numbers

## 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<sup>0</sup>/7 - 35<sup>6</sup>/7 weeks) versus delayed ECV (not before 37<sup>0</sup>/7 weeks) increase or decrease the likelihood of Caesarean Section (CS)?
2. Is the risk of preterm birth (less than 37<sup>0</sup>/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](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/cmcr/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<sup>0</sup>/7 - 35<sup>6</sup>/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**

c/o Sarah Lampson

Clinical Trial Agreements and Contracts Specialist

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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?
<a href="#">Results article</a>	results	01/04/2011		Yes	No
<a href="#">Results article</a>	results	26/09/2014		Yes	No