

# The Twin Birth Study: planned caesarean section versus planned vaginal birth for twins at 32-38 weeks gestation

<b>Submission date</b> 31/10/2003	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 09/12/2003	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 12/03/2020	<b>Condition category</b> 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

### Contact name

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### Contact details

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## Additional identifiers

### ClinicalTrials.gov (NCT)

NCT00187369

### Protocol serial number

MCT-63164

# Study information

## Scientific Title

The Twin Birth Study: a multicentre randomised controlled trial comparing planned caesarean section with planned vaginal birth for twins at 32-38 weeks gestation

## Acronym

TBS

## Study objectives

Twins complicate approximately 2 - 3% of all births. Twin fetuses that are greater than 2500 g at birth are at higher risk of death and neonatal morbidity than singletons of the same birth weight. In addition, the second twin is at higher risk of death and/or serious neonatal morbidity compared with twin A if delivery is vaginal but not if delivery is by caesarean section (CS). There has been one randomised controlled trial (RCT) of planned CS versus planned vaginal birth (VB) for twins: the sample size was too small to answer the question of the better approach to delivery. A Cochrane review has recommended that a larger RCT be undertaken.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Sunnybrook Health Sciences Centre Research Ethics Board, 31/10/2008, ref: 244-2003

## Study design

Randomised controlled trial

## Primary study design

Interventional

## Study type(s)

Treatment

## Health condition(s) or problem(s) studied

Twin pregnancies where the first twin is presenting in the cephalic position.

## Interventions

Women will be randomised to either a planned vaginal birth group or to a planned caesarean section group.

Randomisation will be carried out at 32 weeks, allowing for planning of the delivery and birth. Eligible consenting women presenting in labour or with an indication for urgent delivery may also be randomised at 32 - 38 weeks.

## Timing and Method of Delivery:

Because there is an increase in stillbirth rate after 38 weeks gestation, trial participants will be delivered by the planned method of delivery at 38 weeks. Vaginal delivery will be conducted by experienced personnel: if twin B is non-vertex the initial options for delivery are:

1. Spontaneous or assisted vaginal breech delivery (if breech)
2. Total breech extraction with or without internal podalic version
3. External cephalic version and vaginal delivery of the fetus as a vertex

**Intervention Type**

Procedure/Surgery

**Primary outcome(s)**

Perinatal or neonatal mortality and/or serious neonatal morbidity (excluding lethal congenital anomalies)

**Key secondary outcome(s)**

1. Death or poor neurodevelopmental outcome of the children at 2 years of age
2. Problematic urinary or faecal/flatal incontinence for the mother at 2 years postpartum

Other outcome measures:

1. Maternal death or serious maternal morbidity within 28 days following delivery
2. Maternal satisfaction with method of delivery (3 months)
3. Breast feeding (3 months)
4. Maternal quality of life (3 months and 2 years)
5. Problematic urinary or faecal/flatal incontinence at 3 months
6. Costs

**Completion date**

01/10/2011

**Eligibility****Key inclusion criteria**

1. Women at 32 - 38 weeks gestation
2. Aged 18 - 49 years old, female
3. Carrying live twins that each weigh 1500 - 4000 g
4. First twin is presenting in the cephalic position

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

Female

**Total final enrolment**

2804

**Key exclusion criteria**

1. Monoamniotic twins
2. Lethal anomaly of either twin
3. Contraindication to labour or VB

Added 04/03/2009:

4. Previous participation in the Twin Birth Study

**Date of first enrolment**

13/12/2003

**Date of final enrolment**

04/04/2011

## Locations

**Countries of recruitment**

United Kingdom

Argentina

Australia

Belgium

Brazil

Canada

Chile

Croatia

Egypt

Estonia

Germany

Greece

Hungary

Israel

Jamaica

Jordan

Netherlands

Poland

Romania

Serbia

Spain

United States of America

**Study participating centre**

**The Centre for Mother, Infant, and Child Research**

Toronto

Canada

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## **Sponsor information**

**Organisation**

University of Toronto (Canada)

**ROR**

<https://ror.org/03dbr7087>

## **Funder(s)**

**Funder type**

Research organisation

**Funder Name**

Canadian Institutes of Health Research (CIHR) (Canada) - <http://www.cihr-irsc.gc.ca> (ref: MCT-63164)

**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?
<a href="#">Results article</a>	results	03/10/2013		Yes	No
<a href="#">Other publications</a>	secondary analysis	06/01/2017		Yes	No
<a href="#">Other publications</a>	secondary analysis	01/04/2021	04/11/2019	Yes	No
<a href="#">Other publications</a>	secondary analysis	01/10/2019	12/03/2020	Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes