

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

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

Plain English summary of protocol

Not provided at time of registration

Study website

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

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

NCT00187369

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Patient information material can be found at http://www.sunnybrook.ca/research/?page=sri_proj_cmicr_trial_tbs_info

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 measure

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

Secondary outcome measures

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

Overall study start date

01/05/2003

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

Age group

Adult

Lower age limit

18 Years

Sex

Female

Target number of participants

2800

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

Argentina

Australia

Belgium

Brazil

Canada

Chile

Croatia

Egypt

Estonia

Germany

Greece

Hungary

Israel

Jamaica

Jordan

Netherlands

Poland

Romania

Serbia

Spain

United Kingdom

United States of America

Study participating centre

The Centre for Mother, Infant, and Child Research

Toronto

Canada

M5G 1N8

Sponsor information

Organisation

University of Toronto (Canada)

Sponsor details

The Centre for Mother, Infant, and Child Research

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Sponsor type

University/education

Website

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

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, 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	03/10/2013		Yes	No
Other publications	secondary analysis	06/01/2017		Yes	No
Other publications	secondary analysis	01/04/2021	04/11/2019	Yes	No
Other publications	secondary analysis	01/10/2019	12/03/2020	Yes	No