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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	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 09/12/2003	**Overall study status** Completed	
Last Edited 12/03/2020	**Condition category** Pregnancy and Childbirth	

Plain English summary of protocol
Not provided at time of registration

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

Contact information

Type(s)
Scientific

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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
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Sponsor information

Organisation
University of Toronto (Canada)

Sponsor details
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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