

## PRIMARY RESEARCH QUESTION

For twin pregnancies of 32-38 weeks gestation, where twin A is in cephalic presentation, does a policy of planned caesarean section decrease the likelihood of perinatal or neonatal mortality or serious neonatal morbidity, during the first 28 days after birth, compared to a policy of planned vaginal birth?

## BACKGROUND

Twins complicate approximately 2-3% of all births. Twin fetuses that are >2500g 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 vs 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.

## RESEARCH DESIGN

To eliminate selection bias, a RCT with prognostic stratification for parity and gestational age at randomisation will be used.

## SELECTION CRITERIA

Inclusion Criteria: Women at 32-38 weeks gestation where the estimated weight of each fetus is 1,500g-4,000g with both twins alive. Twin A must be in cephalic presentation.

Exclusion Criteria: Monoamniotic twins, lethal fetal anomaly of either twin, contraindication to labour or vaginal delivery, and previous participation in the Twin Birth Study.

## OUTCOMES

The primary outcome is perinatal or neonatal mortality and/or serious neonatal morbidity (excluding lethal congenital anomalies).

The secondary outcome is death or poor neurodevelopmental outcome of the children at 2 years of age and problematic urinary or faecal/flatal incontinence for the mother at 2 years postpartum.

Additional outcomes include maternal death or serious maternal morbidity within 28 days following delivery, maternal satisfaction with method of delivery (3 months), breast feeding (3 months), maternal quality of life (3 months & 2 years), problematic urinary or faecal/flatal incontinence at 3 months, and costs.

## SAMPLE SIZE

In total, 2800 women (1400/group) are required.

## RANDOMISATION

Randomisation will be carried out at 32-38 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.

Eligible women are randomly allocated, using a centrally controlled, computerised telephone randomisation service.

## TRIAL MANAGEMENT

Recruitment will begin in December 2003 and will be completed in June 2008. Mother and babies will be followed until babies are 24 months of age (adjusted for gestational age).

### Twin Birth Study Steering Committee:

Jon Barrett *Principal Investigator*

Alexander Allen	Eileen Hutton
Anthony Armson	KS Joseph
Elizabeth V Asztalos	Line Leduc
Scott Farrell	Dalah Mason
Amiram Gafni	Arne Ohlsson
Julia E Hanigsberg	Nanette Okun
Mary Hannah	Susan Ross
Sheila A Hewson	Andrew R Willan

If you think that your centre might be interested in participating in the **Twin Birth Study**, please return this form with the following information and we will send you a study protocol and forms to complete:

*please print*

Name \_\_\_\_\_  
(title)

Hospital \_\_\_\_\_

Address \_\_\_\_\_

\_\_\_\_\_ city \_\_\_\_\_ province

\_\_\_\_\_ country \_\_\_\_\_ postal code

Telephone \_\_\_\_\_  
country code/city code/area code

Fax \_\_\_\_\_  
country code/city code/area code

email \_\_\_\_\_

PLEASE RETURN TO:

Twin Birth Study Coordinating Centre  
MIRU  
7<sup>th</sup> Floor, 790 Bay Street  
Toronto, ON CANADA M5G 1N8

or Fax: 1 416 351 3771

or send the above information by email to:  
tbs@sw.ca

**INTERESTED COUNTRIES PLANNING  
TO PARTICIPATE IN THE  
TWIN BIRTH STUDY INCLUDE:**

- Australia
- Canada
- Chile
- Germany
- Israel
- Jordan
- Poland
- Sweden
- The Netherlands
- United Kingdom
- USA

and several other countries worldwide.



Maternal, Infant and Reproductive  
Health Research Unit



CIHR IRSC

This study is funded by the Canadian Institutes of Health Research and coordinated at the Maternal, Infant & Reproductive Health Research Unit at The Centre for Research in Women's Health, Toronto, Canada.

**Information for physicians and  
other healthcare providers**



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