TWIN BIRTH STUDY (TBS)

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.

AIM: To conduct a multicentre international RCT, comparing planned CS to planned VB for twins at 32 - 38 weeks gestation.

METHODS:

Selection criteria: *Inclusion:* twins at 32 - 38 weeks gestation with twin A presenting vertex, both twins alive, and estimated fetal weight 1500-4000g. *Exclusion:* monoamniotic twins, lethal anomaly of either twin, contraindication to labour or VB.

Timing of Randomisation: 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: i) spontaneous or assisted vaginal breech delivery (if breech); ii) total breech extraction with or without internal podalic version; or iii) external cephalic version and vaginal delivery of the fetus as a vertex.

Outcomes: *Primary:* perinatal or neonatal mortality and/or serious neonatal morbidity (excluding lethal congenital anomalies). S*econdary:* i) death or poor neurodevelopmental outcome of the children at 2 years of age; ii) problematic urinary or faecal/flatal incontinence for the mother at 2 years postpartum. *Others:* 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; costs.

Sample Size: A sample of 1400 pregnancies/group will be adequate to find a reduction in risk of perinatal or neonatal mortality or serious neonatal morbidity from 4% to 2% with a policy of planned CS, if such a reduction exists (power = 80%, 2-sided α error = 0.05). To enrol 2800 women over 4.5 years, approximately 120 centres are required.

RESULTS: To date, more than 140 centres in 30 countries have indicated their willingness to join the trial. An application for funding has been approved by the Canadian Institutes of Health Research, with recruitment of eligible women expected to begin late in 2003.

CONCLUSION: TBS appears a feasible trial, that will answer a question of importance to women, clinicians and policy makers. The trial should be undertaken before, in the absence of evidence, CS becomes the standard of care for women with twins.