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Twins - timing of birth at term. A randomised clinical trial

Submission date	Recruitment status	[ ] Prospectively registered
18/03/2005	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
17/06/2005	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
24/09/2012	Pregnancy and Childbirth	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title

Acronym
ACTOTTAB

Study objectives
The primary hypothesis of the trial is that for women with a twin pregnancy elective timing of birth at 37 weeks gestation is associated with a reduction in serious adverse outcome for the infant, defined as one or more of stillbirth, neonatal death or significant infant morbidity.

Please note that, as of 28/08/2009, the anticipated start and end dates of this trial have been updated from 01/05/2005 and 31/08/2008 to 01/02/2003 and 31/12/2010, respectively.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval for the lead centre was obtained from the Women's & Children's Hospital Research Ethics Committee (ref: EC00197). All other centres have obtained ethics approval before recruitment of the first participant.

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Not Specified

Health condition(s) or problem(s) studied
Twins at term

Interventions
Elective birth at 37 weeks gestation compared with standard care

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
A composite mortality and morbidity index has been chosen as the primary outcome for the trial.

For a policy of elective birth at 37 weeks gestation to be justified in clinical practice, there must be an important benefit of reduced perinatal mortality or serious adverse outcome for the infants defined as one or more of the following occurring within six weeks postpartum:
1. Perinatal mortality defined as any fetal death after trial entry, or death of a liveborn infant within 28 days of age (excluding lethal congenital anomalies); or
2. Serious neonatal morbidity defined as one or more of the following, excluding lethal congenital anomalies: birth trauma (subdural or intracerebral haemorrhage, spinal cord injury, basal skull fracture, other fracture, peripheral nerve injury present at discharge from hospital);

birth weight <3rd centile for gestational age at birth and infant sex (Roberts 1999); Apgar score <4 at 5 minutes of age; cord pH <7.18; base deficit (arterial or venous cord blood) >-8; seizures at <24 hours age or requiring two or more drugs to control; neonatal encephalopathy grade 3 or 4 (Sarnat 1976); altered level of consciousness (stupor, decreased response to pain or coma); use of ventilation >24 hours; use of tube feeding >4 days; admission to neonatal intensive care unit (NICU) >4 days; severe respiratory distress syndrome (mean arterial pressure [MAP] >10 and or FiO2 >0.8 with need for ventilation); proven necrotising enterocolitis; proven systemic infection within 48 hours of birth treated with antibiotics.

These definitions of adverse outcome are those used by the Australian and New Zealand Neonatal Network (Donoghue 2000), and those considered by experts as important measures of term and post-term neonatal morbidity (Hannah 1992).

Key secondary outcome(s))
1. Antenatal medical and obstetric defined complications
2. Labour and birth defined complications
3. Adverse outcomes for the infant defined
4. Serious adverse outcome for the woman defined as a composite endpoint of birth
5. Maternal physical wellbeing
6. Maternal emotional wellbeing
7. Maternal satisfaction with care
8. Longer term health, growth and development of the infant

Completion date
31/12/2010

Eligibility

Key inclusion criteria
Women with a twin pregnancy at 37 weeks gestation

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
Women with any of the following will be excluded from the trial: intrauterine fetal death of one or both fetuses at the time of trial entry; active labour; fetal distress or non-reassuring fetal heart rate trace; maternal or fetal compromise precluding continued antenatal surveillance.

Date of first enrolment
01/02/2003

Date of final enrolment
31/12/2010

Locations

Countries of recruitment
Australia

Study participating centre
University Department of Obstetrics and Gynaecology
North Adelaide
Australia
5006

Sponsor information

Organisation
The University of Adelaide (Australia)

ROR
https://ror.org/00892tw58

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Women's & Children's Hospital (Australia)

Results and Publications

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	01/07/2012	Yes	No