

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

Submission date 18/03/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 17/06/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 24/09/2012	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Not Specified

Participant information sheet

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 measure

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).

Secondary outcome measures

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

Overall study start date

01/02/2003

Completion date

31/12/2010

Eligibility

Key inclusion criteria

Women with a twin pregnancy at 37 weeks gestation

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

576

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

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Sponsor information**Organisation**

The University of Adelaide (Australia)

Sponsor details

-

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Sponsor type

University/education

Website

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ROR

<https://ror.org/00892tw58>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Women's & Children's Hospital (Australia)

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	01/07/2012		Yes	No