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Birth After Caesarean - Planned vaginal birth or planned caesarean section for women at term with a single previous caesarean birth

Submission date	Recruitment status	[_] Prospectively registered
06/09/2005	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
05/10/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
07/01/2021	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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title
Birth After Caesarean - Planned vaginal birth or planned caesarean section for women at term with a single previous caesarean birth

Acronym
BAC

Study objectives
For women who meet eligibility criteria for a planned VBAC there is no difference in the risk of death or serious adverse outcome for the infant in women who have a planned VBAC compared with planned elective repeat caesarean.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Birth after previous caesarean

Interventions
Eligible women will be randomised to either planned vaginal birth after caesarean or planned elective repeat caesarean section or can be entered into their preferred treatment group (patient preference study)

Intervention Type

Other

Phase
Not Specified

Primary outcome measure
1. Neonatal lung disease
2. Serious neonatal mobidity
3. Perinatal/neonatal mortality

Secondary outcome measures
Secondary outcome(s) for funded study as of 2005:
1. Serious adverse outcomes for the women (up to time of primary hospital discharge)

Secondary outcomes for pre-funding draft protocol:
1. Serious adverse outcomes for the women
2. Maternal physical wellbeing
3. Maternal emotional wellbeing
4. Costs of health care for the infant

Overall study start date
28/03/2003

Completion date
07/01/2008

Eligibility

Key inclusion criteria
Women with a single prior caesarean presenting in their next pregnancy with a single live fetus in cephalic presentation who have reached 37 weeks gestation, and who don't have a contraindication to a planned VBAC.

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
2314 (including patient preference and RCT arms and allowing for a small 1% loss to follow-up)

Total final enrolment
2345

Key exclusion criteria

Women with more than 1 prior caesarean; vertical inverted T or unknown uterine incision; previous uterine rupture; previous uterine surgery (hysterotomy) or myomectomy with entry into uterine cavity; previous uterine perforation; multiple pregnancy; any contraindication to vaginal birth; cephalo-pelvic disproportion; lethal congenital anomaly; fetal anomaly associated with mechanical difficulties at delivery.

Date of first enrolment
28/03/2003

Date of final enrolment
07/01/2008

Locations

Countries of recruitment
Australia

Study participating centre
University of Adelaide
North Adelaide
Australia
5006

Sponsor information

Organisation
The University of Adelaide (Australia)

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Sponsor type
University/education

Website
http://www.adelaide.edu.au/

ROR
https://ror.org/00892tw58

Funder(s)

Funder type
Research council

Funder Name
Australian National Health and Medical Research Council (NHMRC)

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?
Protocol article	protocol	14/08/2007		Yes	No
Results article	results	01/08/2012	07/01/2021	Yes	No