

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

Submission date 06/09/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 05/10/2005	Overall study status Completed	<input checked="" type="checkbox"/> Protocol
Last Edited 07/01/2021	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<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

Protocol serial number
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

Study type(s)

Not Specified

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(s)

1. Neonatal lung disease
2. Serious neonatal morbidity
3. Perinatal/neonatal mortality

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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)

ROR

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

Funder(s)

Funder type

Research council

Funder Name

Australian National Health and Medical Research Council (NHMRC)

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