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Amniocentesis Before rescue Cerclage

Submission date	Recruitment status	[ ] Prospectively registered
30/10/2007	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
11/01/2008	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
11/01/2008	Pregnancy and Childbirth	[ ] Record updated in last year

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
MSH Reference Number # 07-0080-A

Study information

Scientific Title

Acronym
ABC Trial

Study objectives

We hypothesise that the use of a diagnostic amniocentesis and testing for rapid markers of chorioamnionitis (amniotic fluid lactate dehydrogenase or glucose level) will identify a subset of women without subclinical chorioamnionitis for whom the cerclage is more likely to prolong pregnancy to a viable gestational age and decrease the risk of neonatal and maternal complications.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval is pending as of 31/10/2007.

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Cervical incompetence

Interventions
Women will be randomised to either:
1. Cerclage group
2. Amniocentesis and cerclage group

Randomisation will be organised by a random numbers table and assigned by telephone. Women randomised to the amniocentesis group will undergo an aseptic aspiration of amniotic fluid under ultrasound guidance by a single operator. Briefly, the abdomen will be prepared with antiseptic solution and draped with sterile towels. The ultrasound transducer probe will be draped with a sterile plastic cover. Using a sterile water-based ultrasound gel to facilitate visualisation, the operator will identify a pocket of amniotic fluid suitably away from the foetus and placenta. A sterile 22 gauge needle will be passed into the uterine cavity under direct visualisation and approximately 15 cc of amniotic fluid will be aspirated.

Post procedure, Rhogam™ will be administered to Rhesus negative patients as indicated. Amniotic fluid will be tested for lactate dehydrogenase level (2 cc), glucose level (2 cc), cell count (2 cc), haemoglobin level (2 cc) and Gram staining (2 cc). Amniotic fluid will be sent for confirmatory aerobic, anaerobic and myoplasma/ureaplasma culture (4 cc per culture).

All tests will be performed by the respective Departments of Biochemistry, Haematology and Microbiology (Mount Sinai Hospital, Canada) using established protocols. While waiting for the fluid test results (approximately 90 - 120 minutes), a tocodynometer will be placed over the uterine fundus to confirm the absence of uterine activity. Those women without evidence of subclinical infection following amniocentesis and those women who were randomised to the cerclage group will have a rescue cerclage placed.

Rescue cerclage placement will be performed under general anaesthesia. Women will be placed in the lithotomy position with a steep Trendelenberg tilt. The prolapsed membranes will be gently pushed back into the uterine cavity with an inflated Foley catheter. A single purse string suture (#5 Ticron™) will be performed using the technique described by MacDonald. Perioperative tocolysis (indomethacin 100 mg per rectum [pr] followed by 25 mg orally every 6 hours for 48 hours) to prevent the uterine contractions that can be precipitated by cervical manipulation and cerclage insertion and prophylactic antibiotics (clindamycin 900 mg intravenous [iv] three times a day [TID] for 7 days) will be administered. A transvaginal ultrasound to evaluate the cervical placement will be done 48 hours postoperatively.

Following cerclage insertion, women will be restricted to bedrest until 30 weeks of gestation. Cerclages will be removed electively at 36 weeks or before based on foetal or maternal indication. Thromboprophylaxis with enoxaparin (40 mg subcutaneously [sc] once daily [od]) will be administered to all women on prolonged bed rest.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
The primary comparison will be the prolongation of gestation to greater than 34 weeks of gestation, defined as rescue cerclage success.

Key secondary outcome(s))
1. Maternal morbidity: will include complications of cerclage insertion, through gestation and at the time of the delivery
2. Neonatal morbidity: will include complications during the initial admission to the nursery following the delivery

Completion date
31/12/2008

Eligibility

Key inclusion criteria
1. Singleton gestation
2. Presence of cervical dilatation
3. Membranes visible at or protruding through the cervical opening
4. Absence of any uterine activity
5. Absence of any overt signs of maternal infection:
5.1. Maternal temperature greater than 37.8°C
5.2. Diffuse abdominal pain
5.3. Foul/pus like discharge
5.4. Maternal or foetal tachycardia

Participant type(s)
Patient

Healthy volunteers allowed

No

Age group
Adult

Sex
Female

Key exclusion criteria
1. Intrauterine foetal demise or distress
2. Intrauterine growth restriction
3. Foetal anomaly
4. Poly- or oligo-hydramnious
5. Ruptured foetal membranes
6. Current history of significant antepartum haemorrhage

Date of first enrolment
01/01/2008

Date of final enrolment
31/12/2008

Locations

Countries of recruitment
Canada

Study participating centre
RM 3201
Toronto
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Sponsor information

Organisation
Mount Sinai Hospital (Canada)

ROR
https://ror.org/05deks119

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Mount Sinai Hospital (Canada) - Department of Obstetrics and Gynaecology Research Fund ($5000)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration