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A multicentre randomised controlled trial of amnioinfusion

Submission date 16/11/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 16/11/2005	**Overall study status** Completed	
Last Edited 15/11/2013	**Condition category** Neonatal Diseases	

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
MCT-15221

Study information

Scientific Title
A multicentre randomised controlled trial of amnioinfusion for thickly meconium stained amniotic fluid to reduce the risk of moderate to severe meconium aspiration syndrome or perinatal death

Study objectives
1. To assess when compared to standard care, a policy of amnioinfusion for thickly meconium stained amniotic fluid reduces the risk of either moderate to severe meconium aspiration syndrome or perinatal death
2. To assess the effects of amnioinfusion on the risk of occurrence of other indicators of neonatal morbidity, cesarean section and indicators of severe maternal morbidity
3. Will evaluate the acceptability of amnioinfusion to women and determine the cost-effectiveness of the procedure

Ethics approval required
Old ethics approval format

Ethics approval(s)
University Hospital of Québec Research Ethics Committee approved on the 26th June 2002.

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Meconium aspiration syndrome

Interventions
Experimental: Intrapartum transcervical infusion of 800 ml of sterile normal saline over a period of 40 minutes at 20 ml/min followed by continuous infusion up to total volume of 1500 ml
Control: usual care

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Occurrence of perinatal death or moderate/severe meconium aspiration syndrome.

Secondary outcome measures
Maternal:
1. Haemorrhage requiring blood transfusion
2. Hysterectomy
3. Uterine rupture
4. Febrile morbidity
5. Caesarean section
6. Acceptability of amnioinfusion to women
7. Determine the cost-effectiveness of the procedure

Foetal:
1. Foetal heart rate tracing abnormalities
2. Positive blood or cerebrospinal fluid culture
3. Convulsions
4. Need for tube feeding
5. Fractures and palsies
6. Duration of oxygen supplementation
7. Duration of ventilation
8. Abnormal chest x-ray

Overall study start date
01/04/1999

Completion date
30/04/2002

Eligibility

Key inclusion criteria
1. Pregnant women of childbearing age, with a single baby in cephalic presentation
2. Ruptured membranes (spontaneous or artificial)
3. Gestational age greater than or equal to 36 weeks
4. Established labour defined as the presence of regular contractions occurring at 5 minute intervals
5. Cervical dilation between 2 and 7 cm inclusively at randomisation
6. Thick meconium
7. Foetal status considered as acceptable after a 30-minute period of electronic foetal heart rate monitoring

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
1998

Key exclusion criteria
1. Cord prolapse
2. Known or suspected major foetal anomaly
3. Suspicion of chorioamnionitis on the basis of maternal fever or abnormal vaginal discharge
4. Known placenta praevia or virginal bleeding due to other causes
5. Known intravenous drug user
6. Patient known or suspected to be at high risk of human immunodeficiency virus (HIV)
7. Hepatitis B or C
8. Active genital herpetic lesions
9. Uterine over distension
10. Previous uterine incision other than low transverse
11. Recurrent late decelerations
12. Prolonged decelerations
13. Scalp blood pH less than 7.15
14. Any contradictions to labour
15. Unable to comprehend the consent form
16. Use of narcotic analgesics prior to consent

Date of first enrolment
01/04/1999

Date of final enrolment
30/04/2002

Locations

Countries of recruitment
Argentina

Belgium

Brazil

Canada

France

Mexico

Portugal

South Africa

Switzerland

Tunisia

United Kingdom

United States of America

Uruguay

Study participating centre
Hôpital Sainte-Justine
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Sponsor information

Organisation
Hospital Sainte-Justine, Montréal (Canada)

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Sponsor type
Not defined

ROR
https://ror.org/01gv74p78

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: MCT-15221)

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	01/09/2005		Yes	No