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The Fluid In Low risk Labour Trial

Submission date 06/09/2008	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 29/09/2008	**Overall study status** Completed	
Last Edited 29/09/2008	**Condition category** 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
The effect of conservative versus routine intrapartum fluid management in women with epidural analgesia on breastfed newborn weight loss: a randomised controlled trial

Acronym
The FILL Trial

Study objectives
For low risk women receiving epidural analgesia in labour, what is the effect of a conservative protocol for fluid management versus usual care on breastfed newborns weight loss in the first 48 hours of life?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Research Ethics Board of Sunnybrook Health Sciences Centre on the 21st August 2008 (ref: 237-2008)

Study design
Single site randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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
Fluid management in labour

Interventions
Total duration of treatment is from the time of admission to the labour unit until the time of delivery. Patients will be randomised to one of the following fluid management techniques:

Usual Intrapartum Fluid Management:
Usual intrapartum fluid management includes the initiation of intravenous therapy prior to epidural analgesia administration or when intravenous drugs need to be administered. Fluid preload for epidural analgesia initiation ranges from 500 cc to 1000 cc of Ringers Lactate and intravenous (IV) fluid is administered throughout labour for non-reassuring foetal heart rate tracings and maternal fever. Hourly infusion volumes vary from 125 to 250 ml per hour or greater. Calculations of fluid balance may not be routinely conducted intrapartum but summarised at the time of transfer of the woman to the postpartum floor. Intrapartum assessments do not routinely include hydration assessments or calculation of intrapartum fluid balance.

Conservative Fluid Management:
A conservative intrapartum fluid management protocol will be administered to the experimental group. This protocol assumes that care is individualised to the labouring woman and will be reflective of the events of her labour. Women will receive an epidural analgesia preload of 250 to 500 ml of Ringers Lactate and the intravenous infusion will continue at the hourly rate of 75 to 100 ml per hour. Hydration assessments and fluid balance calculations will be conducted and recorded every four hours. Reaching critical values for fluid infused greater than 2500 ml will require the nurse to review the fluid management plan with the physician responsible for the woman's care, maternal fever will be treated with acetaminophen. Decisions regarding bolus for abnormal foetal heart rate patterns will at the discretion of the caregivers.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Breastfed newborn weight loss in the first 48 hours.

Secondary outcome measures
Breastfeeding exclusivity, measured prior to discharge from the postpartum unit.

Overall study start date
15/10/2008

Completion date
15/10/2009

Eligibility

Key inclusion criteria
1. Women in early labour, 19 - 40 years of age
2. Experiencing a labour at no identified risk
3. Anticipating a vaginal birth
4. Planning to breastfeed
5. Requesting an epidural

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
200

Key exclusion criteria
1. Planning discharge before 48 hours
2. Unable to read and write English
3. Previous breast surgery
4. Expected to deliver in the next 4 - 5 hours

Date of first enrolment
15/10/2008

Date of final enrolment
15/10/2009

Locations

Countries of recruitment
Canada

Study participating centre
98 Bessborough Drive
Toronto
Canada
M4G 3J1

Sponsor information

Organisation
Sunnybrook Health Sciences Centre (Canada)

Sponsor details
2075 Bayview Avenue
Toronto
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Sponsor type
Hospital/treatment centre

Website
http://www.sunnybrook.ca/

ROR
https://ror.org/03wefcv03

Funder(s)

Funder type
Research organisation

Funder Name
Society of Obstetricians and Gynaecologists (Canada) - Strategic Training Initiative in Research in the Reproductive Health Sciences (STIRRHS) Fellowship

Funder Name
Sunnybrook Health Sciences Centre (Canada)

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