

The Fluid In Low risk Labour Trial

Submission date 06/09/2008	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
Registration date 29/09/2008	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 29/09/2008	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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
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

Study type(s)

Treatment

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(s)

Breastfed newborn weight loss in the first 48 hours.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration