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# The Fluid In Low risk Labour Trial

| Submission date | Recruitment status | [X] Prospectively registered |
|---|---|---|
| 06/09/2008 | No longer recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 29/09/2008 | Completed | [_] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 29/09/2008 | 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

## 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)

## Primary study design
Interventional

## Study design
Single site randomised controlled trial

## 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