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# Early feeding compared with on patient demand feeding after planned Caesarean delivery

**Submission date**
20/09/2012

**Recruitment status**
No longer recruiting

**Registration date**
08/10/2012

**Overall study status**
Completed

**Last Edited**
22/01/2019

**Condition category**
Pregnancy and Childbirth

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

## Plain English summary of protocol

Background and study aims
There is still considerable variation in how women are managed with regard to feeding in the period immediately following Caesarean delivery. Some doctors will allow fluids after 6 hours and food only when there is physical evidence of bowel activity like bowel sounds or the passage of wind. In our centre, most doctors allow fluid on return to the ward and food to follow as tolerated. This means that both fluid and food are only started when the patient requests them. It has been shown that starting to drink whilst still in the recovery area (within 30 minutes of Caesarean) is safe and associated with high satisfaction. We believe that encouraging both food and drink when the patient returns to ward immediately after Cesarean, when there is still no pain as the spinal anaesthetic is still effective, will allow a meal to be eaten in comfort and this will allow bowel function to return more quickly. We think that the return of bowel function and the feel good sensation from eating a meal will speed up recovery and generate a feeling of wellbeing. The aim of this study is to evaluate the effects of 'early feeding' in terms of patient satisfaction and intolerability (as demonstrated by vomiting).

Who can take part?
Women admitted for a planned Caesarean delivery under spinal anaesthetic.

What does the study involve?
On return to the ward after their Caesarean delivery, the women are randomly allocated to either early or on demand feeding. Women allocated to early feeding are served food (a sandwich) and fluid as soon as possible after their return to the ward from the operating theatre and asked to consume without delay. Women allocated to on demand feeding are told that food and drink will be served for their consumption on request. In the first 24 hours after the operation we recorded patient satisfaction, any vomiting episodes, feelings of nausea, bloating and pain, time to first passage of wind and first bowel sound, use of anti-emetic (anti-vomiting) drugs, time to removal of urinary catheter/passing urine, length of hospital stay, and use of additional pain relief. We ask the patients whether they would recommend their allocated feeding regimen to a friend, and whether they would prefers to be fed as soon as possible or at their own pace in a future Caesarean.

What are the possible benefits and risks of participating?
It is possible that early feeding may cause nausea and vomiting. If this happens patients will be given medication to help with these symptoms.

When does the study take place?
August 2012 to August 2013.

Where does the study take place?
University of Malaya Medical Centre (Malaysia).

Who is funding the project?
The study is funded by an internal research grant from the University of Malaya (Malaysia).

Who is the main contact?
Dr Aizura Adlan

# Contact information

### Type(s)
Scientific

### Contact name
Dr Aizura Syafinaz Ahmad Adlan

### Contact details
University of Malaya
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50603

# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
931.7

# Study information

### Scientific Title
Early feeding versus on demand feeding after planned Caesarean delivery: a randomised trial

### Study objectives

Early (as soon as returned to the ward from the operating theatre) compared with on demand feeding after an uncomplicated planned Caesarean delivery under spinal anaesthesia will result in a faster return to normal bodily function and be well tolerated. Hence it is anticipated that patient satisfaction will increase and vomiting frequency not impacted by early feeding.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
University of Malaya Medical Centre Medical Ethics Committee, 19/07/2012, ref: 931.7

## Study design
Randomised controlled trial

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
Hospital

## Study type(s)
Quality of life

## 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
Caesarean section

## Interventions
Early feeding with food and fluid served to the patient for immediate consumption as soon as possible after patient returns to the ward OR On demand feeding with food and fluid served to the patient on the ward only as requested by the patient.

## Intervention Type
Other

## Phase
Not Applicable

## Primary outcome measure
1. Patient satisfaction using a 10 cm Visual Analog Scale (VAS)
2. Vomiting episodes in the first 24 hours post operation

## Secondary outcome measures

1. Nausea Verbal Numerical Rating Scale (VNRS) score at 8, 16 and 24 hours
2. Bloating VNRS score at 8, 16 and 24 hours
3. Pain VNRS score at 8, 16 and 24 hours
4. Passage of first flatus
5. First bowel sound
6. Anti-emetic use post delivery
7. Time to mobilization
8. Time to removal of urinary catheter/passing urine
9. Length of hospital stay
10. Additional analgesia in first 24 hours

Questionnaire at 24 hours:
1. Recommend feeding regimen to a friend: 5-point Likert scale
2. In a future Caesarean: prefer to be fed as soon as possible/at my own pace

### Overall study start date
24/08/2012

### Completion date
23/08/2013

## Eligibility

### Key inclusion criteria
1. Admitted for a planned caesarean delivery
2. Age ≥ 18 years
3. Spinal anaesthesia
4. Singleton viable pregnancy
5. Gestation ≥ 37 weeks

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Sex
Female

### Target number of participants
443 women

### Key exclusion criteria
1. Major placenta praevia
2. No concurrent severe medical problems
3. Complicated Caesarean delivery
3.1. Significant intra-abdominal adhesions

3.2. Blood loss > 800 ml
3.3. Bowel, bladder or ureteric injury
3.4. Myomectomy
3.5. Hysterectomy
3.6. Significant adnexal surgery
4. Atonic uterus during Caesarean
5. Adherent placenta
6. Ongoing concern about post Caesarean haemorrhage
7. Any intra-operative development precluding early feeding as identified by provider
8. Magnesium sulphate infusion

### Date of first enrolment
27/08/2012

### Date of final enrolment
23/08/2013

## Locations

### Countries of recruitment
Malaysia

### Study participating centre
**University of Malaya**
Kuala Lumpur
Malaysia
50603

## Sponsor information

### Organisation
University of Malaya (Malaysia)

### Sponsor details
Lembah Pantai
Kuala Lumpur
Malaysia
50603

### Sponsor type
University/education

### Website
http://www.umhtmc.com

**ROR**
https://ror.org/00rzspn62

# Funder(s)

**Funder type**
University/education

**Funder Name**
University of Malaya (Malaysia) ref: RG450_12HTM

**Alternative Name(s)**
University of Malaya, University Malaya, Malayan University, King Edward VII College of Medicine, Raffles College, University of Malaya in Singapore, , , , UM

**Funding Body Type**
Government organisation

**Funding Body Subtype**
Universities (academic only)

**Location**
Malaysia

# 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**

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 01/01/2017 | 22/01/2019 | Yes | No |