

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

Submission date 20/09/2012	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 08/10/2012	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 22/01/2019	Condition category Pregnancy and Childbirth	<input type="checkbox"/> 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 prefer 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

Department of Obstetrics & Gynaecology

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Malaysia

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, 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

Not provided at time of registration

Study outputs

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