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Immediate versus on-demand oral feeding after emergency caesarean delivery in labour

Submission date
01/10/2021

Recruitment status
No longer recruiting

Registration date
04/10/2021

Overall study status
Completed

Last Edited
16/02/2024

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
Early food and drink intake after a Caesarean section has positive benefits on early recovery with no complications. The aim of this study is to find out whether immediate feeding or on-demand feeding improves patient satisfaction and to see the overall characteristics of patients' recovery after surgery. This is an important area for future improvement in the management of Caesarean delivery.

Who can participate?
Pregnant women aged 18 – 45 years in labour with no serious medical illnesses who undergo an emergency Caesarean section without complications and no known risk for immediate repeated surgery

What does the study involve?
The participants will be given a sandwich meal and 250 ml drink of their choice upon returning from the operation theatre after delivery, either immediately or on-demand. The postoperative course and maternal satisfaction are assessed before hospital discharge.

What are the possible benefits and risks of participating?
There may or may not be any benefits to participants. Information obtained from this study will help improve standard practice for women undergoing emergency Caesarean section. Early oral intake after surgery is expected to be safe as the guidelines encourage it and based on a recent study the risk of vomiting is low. Patients will be assessed from time to time and allowed for repeated meals and drinks. Patients may have a higher risk of vomiting; those patients will be monitored and medication to prevent and stop vomiting will be given accordingly.

Where is the study run from?
University of Malaya Medical Center (Malaysia)

When is the study starting and how long it is expected to run for?
July 2021 to January 2023

Who is funding the study?
University of Malaya Medical Center (Malaysia)

Who is the main contact?
Dr Nurulhuda binti Ahmad Sani
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
2021827-10517

Study information

Scientific Title
Immediate versus on-demand maternal full feeding after unplanned caesarean section in labour: a randomised trial

Acronym
ImFLUCS

Study objectives
Immediate feeding for women after an unplanned caesarean section will increase overall maternal satisfaction but will not increase vomiting.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 22/09/2021, University of Malaya Medical Centre, Kuala Lumpur – Medical Research Ethics Committee (UMMC-MREC, Lembah Pantai, 59100, Kuala Lumpur, Malaysia; +60 (0) 379493209; ummc-mrec@ummc.edu.my), ref: MREC ID No: 2021827-10517

Study design
Single-centre open-label randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
https://drive.google.com/file/d/1G8IrflNQDErmGO8_Spv8BgJuzVNbCSIb/view?usp=sharing

Health condition(s) or problem(s) studied
Maternal recovery post unplanned caesarean delivery

Interventions
The study will be conducted in the labour suite and postnatal ward at UMMC. The potential participants will receive standard care during labour. Women who consented to participate and undergo emergency caesarean section will be given a sandwich meal and 250 ml drink of their choice upon returning from operation theatre after delivery, either immediately or on-demand.

Participants will be randomised into two arms (1:1) via labelled opaque envelopes. Randomisation will be generated by a random sequence generator, provided by random.org. to avoid bias, in blocks of 4 and 8.

At this point sealed envelope (intention to treat) which reveals their allocated oral feeding plan, either immediate full feeding or on-demand feeding. The lowest number of the sealed envelope will be taken.

A: Sandwich meal and 250 ml drink of their choice given as soon as possible upon returning to labour suite or postnatal ward while the regional anaesthesia still in action. They should consume as much as they can.
B: Sandwich meal and 250 ml drink of their choice served on demand. They should consume as much as they can.

Post-operative outcomes and maternal satisfaction will be collected prior to discharge.

Intervention Type
Behavioural

Primary outcome measure
Current primary outcome measure as of 18/10/2021:
1. Overall maternal satisfaction with the given oral feeding regimen measured using a numerical rating score (VNRS) 0-10 (higher score = higher satisfaction) prior to hospital discharge
2. Vomiting rate in the first 24 hours post-operative collected from patient's vomiting diary prior to discharge

Previous primary outcome measure:
1. Overall maternal satisfaction with the given oral feeding regimen measured using a 10 cm visual numerical rating score (VNRS) Score 0-10 (higher score higher satisfaction) prior to hospital discharge

2. Vomiting rate in the first 24 hours post-operative collected from patient's diary prior to discharge

Secondary outcome measures

Current secondary outcome measures as of 18/10/2021:
1. Time to first feed, measured by taking the time the participant starts taking orally
2. Food quantum consumed at first feed, quantified by a 6-point scale collected after the first feed
3. Fluid quantum consumed at first feed, quantified by a 6-point scale collected after the first feed
4. Pain, nausea and bloating measured using a horizontal visual numerical rating scale (VNRS, scored 0-10) to score the initial intensity of symptoms (low score, less intense symptom), at 30 minutes after first feed, 8, 16, 24 hours and after 24 hours postoperative up to hospital discharge
5. Opiate analgesia usage collected from hospital records (yes or no and frequency of usage) before discharge
6. Parenteral anti-emetic usage collected from hospital records (yes or no and frequency of usage) before discharge
8. First breastfeeding time collected at 4 - 48 hours post op review by asking the participant her time of first latching and satisfactory breastfeeding. The response taken from the participant on satisfactory breastfeeding is their own term of satisfaction
9. First bowel sound collected at 4 - 48 hours post-op review by auscultation of bowel sounds every 4 hours. The first bowel sound noticed will be recorded
10. First passage of flatus collected at 4 - 48 hours post op review by asking the participant the timing and date
11. Second mealtime collected at 4 - 48 hours post op review by asking the participant the timing and date
12. Cessation of IV fluid time collected from hospital record before discharge
13. Removal of urinary catheter (CBD) collected from hospital records before discharge (the timing and date)
14. First urination after CBD removal collected by asking the participant the timing and date at 4 - 48 hours post op review
15. Ambulation time collected from hospital records and by asking the participants the timing and date before discharge
16. Vomiting during the postoperative stay collected from the patient's diary before discharge (yes or no, frequency of vomiting)
17. Maternal complications collected from hospital records upon discharge

Previous secondary outcome measures:
1. Time to first feed, measured by taking the time the participant starts taking orally
2. Food quantum consumed at first feed, quantified by a 6-point scale collected after the first feed
3. Fluid quantum consumed at first feed, quantified by a 6-point scale collected after the first feed
4. Pain, nausea, vomiting and bloating measured using a diary to record symptoms with yes or no answer and a horizontal visual numerical rating scale (VNRS, scored 0-10) to score the initial intensity of symptoms (low score, less intense symptom), at 30 minutes after first feed, 8, 16, 24 hours and after 24 hours postoperative up to hospital discharge
5. Opiate analgesia usage collected from hospital records (yes or no and frequency of usage) before discharge
6. Parenteral anti-emetic usage collected from hospital records (yes or no and frequency of usage) before discharge

7. First analgesia in ward collected from hospital records by date and time before discharge
8. First breastfeeding time collected at 4 - 48 hours post op review by asking the participant her time of first latching and satisfactory breastfeeding. The response taken from the participant on satisfactory breastfeeding is of their own term of satisfaction
9. First bowel sound collected at 4 - 48 hours post-op review by auscultation of bowel sound every 4 hours for its presence. First bowel sound noticed will be recorded
10. First passage of flatus collected at 4 - 48 hours post op review by asking the participant the timing and date
11. Second mealtime collected at 4 - 48 hours post op review by asking the participant the timing and date
12. Cessation of IV fluid time collected before discharge from hospital record and asking ward provider
13. Removal of urinary catheter (CBD) collected before discharge from hospital record and by asking participants and ward provider the timing and date
14. First urination after CBD removal collected at 4 - 48 hours post op review by asking the participant the timing and date
15. Ambulation time collected before discharge from hospital record and by asking the participants and ward provider the timing and date
16. Vomiting during the post-operative stay collected from patient's diary before discharge (yes or no, frequency of vomiting)
17. Maternal complications collected from hospital records upon discharge

Overall study start date
01/07/2021

Completion date
16/01/2023

Eligibility

Key inclusion criteria
1. Women in labour (cervical dilatation ≥3 cm, contraction ≥2 in 10 minutes)
2. Age 18 – 45 years
3. Singleton pregnancy
4. Gestation ≥37 weeks
5. Unplanned caesarean section
6. Regional anaesthesia
7. No instruction from the surgeon for postoperative Nil By Mouth (NBM)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
45 Years

Sex
Female

Target number of participants
500

Total final enrolment
501

Key exclusion criteria
1. Placenta praevia
2. Multiple pregnancy
3. Diabetes requiring insulin therapy
4. Maternal medical problem that requires fluid restriction
5. Patient who is suspected COVID-19 infection or COVID-19 positive
6. Estimated blood loss >1.5 l
7. Additional surgery needed (e.g., myomectomy, cystectomy, bladder or bowel repair)
8. HDU or ICU admission
9. Significant risk of re-laparotomy
10. Appeared distressed and potentially unable to provide informed consent. i.e. in severe pain

Date of first enrolment
18/10/2021

Date of final enrolment
14/01/2023

Locations

Countries of recruitment
Malaysia

Study participating centre
University of Malaya Medical Centre (UMMC)
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Sponsor information

Organisation
University of Malaya

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Sponsor type
University/education

Website
https://www.um.edu.my/

ROR
https://ror.org/00rzspn62

Funder(s)

Funder type
University/education

Funder Name
Universiti Malaya

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
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date

01/01/2024

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Nurulhuda binti Ahmad Sani (huda.sani@ummc.edu.my, nurul9613@uitm.edu.my).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol (other)		27/08/2021	04/10/2021	No	No
Results article		25/05/2023	16/02/2024	Yes	No