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What is the effect on nausea and vomiting during and after surgery of allowing patients to drink water freely before having a Caesarean section, compared to not eating or drinking for 6+ hours?

Submission date 29/09/2020	**Recruitment status** No longer recruiting	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 01/10/2020	**Overall study status** Completed	
Last Edited 27/11/2023	**Condition category** Surgery	

Plain English summary of protocol

Background and study aims

A Caesarean section is an operation to deliver a baby through a cut made in the tummy and womb.

Women going for Caesarean section require anesthesia of the lower body.

All patients planned for elective Caesarean section are traditionally not allowed to eat or drink (fast) from 12 midnight before the operation. This is because when the anesthetic is used, the body's reflexes are temporarily stopped. If the stomach has food and drink in it, there's a risk of vomiting.

Several studies have proven that allowing patients to drink water up to the surgery call time is most effective in reducing the rate of nausea and vomiting hence improving the recovery time after surgery. However, the traditional practice is to keep patients fasted for a minimum of 6 hours. This study should prove that allowing pregnant patients to consume clear fluids until surgery call time will reduce the rate of vomiting and improve satisfaction rate.

Who can participate?

Pregnant women, more than or equal to 18 years of age, who are planned for elective caesarean section, who are not in labour.

What does the study involve?

Participants will be randomly allocated to 2 groups:

1. Kept fasted from 12 midnight before the operation
2. Light food up to 2am and water up to surgery call time

Participants will be closely monitored before, during, and after their surgery.

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 all women going for elective caesarean sections.
For those who are kept fasted from midnight, there is a risk of hunger and thirst. They will be assessed from time to time and if required they will be administered fluids. For those patients who are allowed to take water freely till surgery call time they may be a very small risk of vomiting, those patients will be monitored and treatment will be given accordingly.

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

When is the study starting and how long is it expected to run for?
October 2019 to May 2022

Who is funding the study?
University Malaya (Malaysia)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
54826 -S1

Study information

Scientific Title
Preoperative standard fasting as opposed to free access to oral water in elective Caesarean sections – a randomised trial

Study objectives

Patient allowed to drink clear fluids up to operating theater (OT) call time have a lower vomiting rate and better satisfaction rate.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 28/9/2020, Medical Research Ethics Committee (Institute of Research Management & Services (IPPP), Level 7, Research Management & Innovation Complex, University of Malaya, 50603 Kuala Lumpur; +60 03-79493209; ummc@ummc.edu.my), ref: 2020623-8813

Primary study design
Interventional

Study design
Single-centre clinical interventional randomized controlled trial

Study type(s)
Other

Health condition(s) or problem(s) studied
Nausea and vomiting associated with regional anesthesia during elective Caesarean section

Interventions
Current intervention as of 29/12/2020:
Patients who have agreed to participate in the study will be randomised into two groups:
1. Kept fasted from 12 midnight before the operation
2. Light food up to 2 am and clear fluid (water) up to OT call time

Patients from both the groups would be given standard aspiration prophylaxis at OT call time as per anaesthetic protocol – Mist Sodium citrate, IV Metaclopromide and IV Ranitidine

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Previous intervention:
Patients who have agreed to participate in the study will be randomised into 2 groups:
1. Kept fasted from 12 midnight before the operation
2. Light food up to 6 hours, clear fluids up to OT call time (max 500 ml of water)

Patients from both the groups would be given standard aspiration prophylaxis at OT call time as per anaesthetic protocol – Mist Sodium citrate, IV Metaclopromide and IV Ranitidine

Intervention Type
Other

Primary outcome(s)
Current primary outcome measures as of 29/12/2020:
1. Presence of vomiting (assessed as yes or no) defined as any vomiting from the time of entry to OT up to 6 h after surgery
2. Patient satisfaction with the feeding strategy assessed on the day of discharge using a verbal numerical rating scale (VNRS) from 0 to 10

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Previous primary outcome measures:
1. Vomiting intraoperative = yes or no (any vomiting from the time of entry to OT until 6 hours after the start of the surgery)
2. Patient satisfaction – VNRS score 0 to 10 - assessed at day 1 post-operation

Key secondary outcome(s)

Current secondary outcome measures as of 29/12/2020:
1. Vomiting (yes or no):
1.1. Preoperative: Any vomiting from midnight to entry to OT
1.2. Intra-operative: Any vomiting from the time of entry to OT to OT end time
1.3. Immediate post-op: Any vomiting from the 6 h post-op up to 24 h post-op
1.4. Post-op Day 1: Any vomiting from 24 h post-op up to time of discharge
2. Feeling thirsty measured using VNRS (0 to 10) upon arrival to OT
3. Feeling hungry measured using VNRS (0 to 10) upon arrival to OT
4. Feeling nauseous measured using VNRS (0 to 10) upon arrival to OT
5. Blood glucose measured using Reflo at OT call time
6. Ketonuria or glycosuria measured using urine dipstick upon arrival to OT
7. Requirement for IV hydration (yes or no – based on clincal judgement) in ward and in reception
8. Heaving /retching (sub-vomiting) (yes or no) during the post-spinal to intraoperative interval
9. Blood pressure (mmHg) during the post-spinal to intraoperative interval
10. Medication given to maintain blood pressure during the post- spinal to intraoperative interval
11. Nausea measured using VNRS (0 to 10) post-op in OT
12. Post operation time to:
12.1. First oral feed
12.2. First flatus
12.3. Sitting up
12.4. Ambulation
13. Resting pain score (day 1 before mobilisation) VNRS 0 to 10
14. Maternal fever to discharge (>38°C)
15. Maternal complications:
15.1. Indication for admission to maternal ICU
15.2. Aspiration pneumonitis
15.3. Mallory-Weiss tear
16. Neonatal parameters:
16.1. Apgar score at 1 and 5 min
16.2. Birth weight
16.3. Indication for admission to neonatal ICU prior to maternal discharge

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Previous secondary outcome measures:
1. Vomiting (yes or no):
1.1. Preoperative: Any vomiting from the time of fast from midnight to entry to OT
1.2. Intra operative: Any vomiting from the time of entry to OT to OT end time
1.3. Immediate post op: Any vomiting from the end of OT time till 24 hours post-op
1.4. Post op Day 1: Any vomiting from 24 hours post-op until time of discharge
2. Feeling thirsty measured using VNRS (0 to 10) upon arrival to OT
3. Feeling hungry measured using VNRS (0 to 10) upon arrival to OT
4. Feeling nauseous measured using VNRS (0 to 10) upon arrival to OT
5. Blood glucose measured using Refloflux upon arrival to OT

6. Ketonuria or glycosuria measured using urine dipstick upon arrival to OT
7. Nausea measured using VNRS (0 to 10) post-op in OT
8. Requirement for IV hydration (yes or no – based on clincal judgement) in ward and in reception
9. Heaving /retching (sub-vomiting) (yes or no) during the post- spinal to intraoperative interval
10. Blood pressure (mmHg) during the post-spinal to intraoperative interval
11. Medication given to maintain blood pressure during the post- spinal to intraoperative interval
Post operation time to:
12. First oral feed
13. First flatus
14. Resting pain score (day 1 before mobilisation) VNRS 0 to 10
15. Interval from surgery to ambulation
16. Maternal fever to discharge (>38°C)

Completion date
24/05/2022

Eligibility

Key inclusion criteria
1. Patients planned for elective Caesarean section
2. Age of >18 years
3. Gestational age of >37 weeks
4. Receiving spinal anesthesia
5. Singleton pregnancy
6. Reassuring fetal status (normal fetal heart tracing)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
Female

Key exclusion criteria
Current exclusion criteria as of 05/01/2021:
1. BMI >40 kg/m²
2. Placenta Praevia Major
3. Placenta accreta
4. Twins and multiple births
5. Emergency Caesarean sections
6. Patients in labour or having contractions
7. DM in pregnancy requiring insulin therapy

8. Anticipated significant risk of extended surgery (e.g intra-abdominal adhesions, myomectomy)
9. Anticipated significant conversion risk to general anaesthesia
10. Anticipated high risk of perioperative vomiting
11. Anticipated ICU admission
12. COVID-positive

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9. Anticipated significant conversion risk to general anaesthesia
10. Anticipated high risk of perioperative vomiting
11. Anticipated ICU admission

Date of first enrolment
02/10/2020

Date of final enrolment
10/05/2022

Locations

Countries of recruitment
Malaysia

Study participating centre
University of Malaya
Department of Obstetrics and Gynecology
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Sponsor information

Organisation
University of Malaya

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, 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

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

IPD sharing plan summary
Available on request