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Free intake of water compared to carbohydrate beverage up to patient despatch from the ward to the operating theatre for planned Caesarean section

Submission date
04/04/2022

Recruitment status
No longer recruiting

Registration date
08/04/2022

Overall study status
Completed

Last Edited
08/04/2022

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Recent trial data suggest that free access to water for drinking until despatch to operating theatre compared to fasting just before Caesarean section reduces vomiting during the delivery and in the 6 hours after the operation. There is evidence in other pre-anaesthesia settings that beverages containing carbohydrate compared to water can improve the patient's condition and their recovery from surgery. Mothers who undergo caesarean section are less successful at breastfeeding compared with those experiencing vaginal delivery. The aim of this study is to find out whether drinks containing carbohydrate before Caesarean section can help establish satisfactory breastfeeding more rapidly compared to water.

Who can participate?
Pregnant women aged 18 years and over at term admitted to the antenatal ward for planned caesarean section

What does the study involve?
Participants are randomly allocated to either free access to water or a carbohydrate beverage to drink from 2 am of the morning of their Caesarean until up to call for despatch to the operating theatre. The number of satisfactory breastfeeding episodes is measured on the day after Caesarean (8 am to 8 am) and maternal satisfaction is assessed.

What are the possible benefits and risk of participating?
A possible benefit is that giving a carbohydrate beverage before the Caesarean will improve the patients' condition and allow a more rapid establishment of breastfeeding. It is possible that vomiting may be increased with the carbohydrate beverage or water.

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

When is the study starting and how long is it expected to run for?
September 2020 to May 2023

Who is funding the study?
Department of Obstetrics & Gynaecology, Universiti Malaya (Malaysia)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Preoperative free access to water compared to carbohydrate beverage to drink up to despatch to the operating theatre in planned Caesarean section

Study objectives
Women who are allocated carbohydrate beverage compared to water until their despatch to the operating theatre will have more episodes of satisfactory breastfeeding and express greater

satisfaction on their preoperative oral intake care experience on the day following their Caesarean delivery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 17/03/2021, University Malaya Medical Centre Medical Ethics Committee (Medical Research Ethics Committee, University Malaya Medical Centre, Lembah Pantai, 59100 Kuala Lumpur, Malaysia; +60 (0)3 79493209/2251; email: not available), ref: 2021222-9864

Study design
Single-centre randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Women admitted to hospital and awaiting planned Caesarean section

Interventions
Participants are randomised using sealed opaque envelopes to either:
A: No solids from 2 am of the morning of the planned Caesarean and free access to drink a carbohydrate beverage from 2 am of the morning of Caesarean until despatch to the operating theatre from the ward
B: No solids from 2 am of the morning of the planned Caesarean and free access to drink water from 2 am of the morning of Caesarean until despatch to the operating theatre from the ward

Participants will be followed up for 3 days (on the day of the operation, day 1 after the operation and day 2 after the operation).

Intervention Type
Behavioural

Primary outcome measure
1. Number of satisfactory breastfeeding episodes on the day after Caesarean until day 2 post-operation (8 am to 8 am), measured using a breastfeeding diary recording times, episode duration and whether the participant perceived the episode to be satisfactory from her

perspective
2. Maternal satisfaction with preoperative oral intake care experience measured using Numerical Rating Scale (NRS 0-10) ratings on thirst, hunger and nausea at ward despatch to operating theatre

Secondary outcome measures
1. Vomiting assessed using a questionnaire from prior to caesarean at arrival to the operating theatre (OT) to exit to OT recovery, at arrival OT recovery to exit to postnatal ward, and pre-discharge from ward
2. Sensation of thirst, hunger and nausea assessed using a numeric rating scale (0 to 10) at despatch to operating theatre
3. Capillary blood glucose level measured using a glucometer at despatch to operating theatre
4. IV rehydration (preoperative) measured using a questionnaire at the OT reception/waiting area
5. Intraoperative heaving/retching (sub-vomiting) measured using a questionnaire (none /heaving or retching/vomiting) during surgery
6. Intraoperative hypotension measured using a questionnaire pre-spinal/intraoperative
7. Post-Caesarean interval to first oral feed measured using a questionnaire after surgery
8. Post-Caesarean interval to first flatus measured using a questionnaire after surgery
9. Post-Caesarean interval to ambulation measured using a questionnaire after surgery
10. Post-Caesarean interval to hospital discharge measured using a questionnaire after surgery
11. Pain at rest measured using a numeric rating scale (0 to 10) at 8 am Day 1 post operation
12. Satisfactory breastfeeding episodes after Caesarean to 8 am Day 1, measured using a patient-completed breastfeeding diary
13. Maternal satisfaction with preoperative oral intake measured with a patient-completed numeric rating scale (0 to 10) at 8 am Day 1
14. Maternal satisfaction with breastfeeding experience measured with a patient-completed questionnaire (satisfactory/unsatisfactory) on Day 1
15. Neonatal outcome assessed using the Apgar score 0-10 at 1 minute and 5 minutes after delivery (completed by doctor or nurse)
16. Umbilical arterial blood pH recorded on questionnaire after delivery (completed by doctor or nurse)
17. Neonatal admission and indication recorded on a questionnaire (completed by doctor or nurse) at the point of after delivery until discharge
18. Maternal fever: highest maternal temperature recorded by doctor or nurse up to hospital discharge
19. Maternal major harm of ICU admission, aspiration or Mallory Weiss tear recorded on a questionnaire (completed by doctor or nurse) during surgery, post surgery and until discharge

Overall study start date
01/09/2020

Completion date
01/05/2023

Eligibility

Key inclusion criteria
1. Admitted for planned Caesarean section
2. Age ≥18 years
3. Gestational age ≥37 weeks

4. Planned spinal anaesthesia
5. Singleton pregnancy
6. Reassuring fetal status (normal fetal heart rate tracing)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
220

Key exclusion criteria
1. BMI >35 kg/m²
2. Placenta praevia
3. Placenta accreta spectrum
4. In labour or having contractions
5. Diabetes requiring insulin
6. Anticipated extended surgery
7. Anticipated significant conversion risk to general anesthesia
8. Anticipated intensive care unit admission
9. Patient who is suspected of COVID-19 infection or SARS-CoV-2 positive

Date of first enrolment
01/05/2022

Date of final enrolment
30/04/2023

Locations

Countries of recruitment
Malaysia

Study participating centre
Pusat Perubatan University Malaya
Jln Profesor Diraja Ungku Aziz
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Sponsor information

Organisation
University Malaya Medical Centre

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Sponsor type
Hospital/treatment centre

Website
http://www.ummc.edu.my/#

ROR
https://ror.org/00vkrxq08

Funder(s)

Funder type
University/education

Funder Name
University Malaya Medical Centre

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
30/04/2023

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date