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The effect of water or a carbohydrate drink on patient discomfort and satisfaction before elective gynaecology surgery

Submission date 12/05/2021	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 17/05/2021	**Overall study status** Completed	
Last Edited 31/01/2022	**Condition category** Surgery	

Plain English summary of protocol

Background and study aims
The aim of this study is to evaluate the effects of free access to water compared to free access to carbohydrate drink before surgery on discomfort, satisfaction and recovery. The study is important to show the difference in the outcome between both these groups to help improve practice in future.

Who can participate?
Women aged over 18 undergoing elective gynaecological surgery under general anaesthetic

What does the study involve?
Participants are allocated at random (by chance alone) to receive either carbohydrate drink or water until operation theatre (OT) call time. Questionnaires are used to assess discomfort, satisfaction and recovery after surgery. Participants will be involved in this study from 12 midnight from the day of the operation until discharge from hospital.

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 going for elective gynaecological surgery. Both drinks are expected to be safe as the guidelines indicate patients are allowed clear fluids up to 1 hour before surgery and based on a recent study the risk of stomach contents entering the lungs is low. Patients will be assessed from time to time and if required they will be started on intravenous fluids. Patients may have a very small 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?
Pusat Perubatan Universiti Malaya (Malaysia)

When is the study starting and how long is it expected to run for?
March 2021 to June 2022

Who is funding the study?
Pusat Perubatan Universiti Malaya (Malaysia)

Who is the main contact?
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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
2021323-9975

Study information

Scientific Title
Preoperative oral water as opposed to free access to oral carbohydrate drink in elective gynaecology surgery: a randomised trial

Study objectives
Patients who are allowed a carbohydrate drink until operating theatre (OT) call time have improved discomfort and satisfaction.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 10/05/2021, Medical Research Ethics Committee, University of Malaya Medical Centre (Jln Profesor Diraja Ungku Aziz, 59100 Kuala Lumpur, Malaysia; +60 (0)3 7949 3209/2251; iresearch@ummc.edu.my), ref: 2021323-9975

Study design
Open-label single-centre prospective randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
See additional file ISRCTN89731226_PIS_v1_25Mar2021 (added 01/06/2021)

Health condition(s) or problem(s) studied
Elective gynaecology surgery

Interventions
Participants will receive usual care. Prior to the operation they will be seen by the anaesthetic team and assessed after which they will be given a date for elective admission to the ward 1 day prior to the surgery. Final eligibility for entry to the study will only be done on the day of admission 1 day prior to the operation. In the ward after being assessed by the anaesthetic team and the gynaecology team in charge and confirmed for operation the next day. At this point they will be given a sealed envelope with a number which will determine the study protocol they need to follow, either free access to water or free access to a carbohydrate drink until their operating theatre (OT) call time.

Intervention Type
Other

Primary outcome measure
1. Hunger measured using verbal numerical rating scale (VNRS) 0 to 10 at OT call time
2. Patient satisfaction measured using VNRS 0 to 10 at OT call time

Secondary outcome measures
Current secondary outcome measures as of 11/01/2022:
1. Measured using a questionnaire:
1.1. Feeling thirsty at OT call time measured using a verbal numerical rating scale (VNRS) 0 to 10 at OT call time (baseline)
1.2. Feeling nauseous at OT call time measured using verbal numerical rating scale VNRS 0 to 10 OT call time (baseline)
1.3. Vomiting (yes or no) measured at OT call time and at first oral feed postoperatively

(baseline)
2. Capillary blood sugar measured using a capillary blood glucose monitoring device at OT call time (baseline)
3. Measured using urine dipstick at OT call time (baseline)
3.1. Ketonuria: nil, 1+, 2+, 3+, 4+ at OT call time (baseline)
3.2. Glycosuria: nil, 1+, 2+, 3+, 4+ at OT call time (baseline)
4. Post-general anesthesia (GA) to intraoperative interval: blood pressure pre GA (baseline), lowest intraoperative blood pressure measured on an automated blood pressure monitoring device, medication needed to maintain blood pressure in OT prior to intubation measured using medical records
5. Usage of antiemetics measured using chart on drug dosage and number of times administered preoperative, intraoperative and postoperative
6. Post-operation time to first oral feed and first flatus measured using medical records at baseline
7. Resting pain score measured using VNRS 0 to 10 on day 1 before mobilization (baseline)
8. Interval from surgery to ambulation measured using medical records at baseline
8.1. Post-operation time to sitting up, measured at baseline
8.2. Post-operation time to walking, measured at baseline
8.3. Passing urine for the first time after removal of catheter, measured at baseline
9. Fever (≥38°C) measured using medical records postoperatively (baseline)
10. Operation to discharge interval: number of days of admission measured using medical records
11. Major complications measured using medical records postoperatively
11.1. ICU admission: yes/no - number of days of admission
11.2. Aspiration pneumonitis: yes /no
11.3. Mallory Weiss tear: yes /no

Previous secondary outcome measures:
1. Measured using a questionnaire:
1.1. Feeling thirsty at OT call time measured using a verbal numerical rating scale (VNRS) 0 to 10 at 0 hours (at OT call time)
1.2. Feeling nauseous at OT call time measured using verbal numerical rating scale VNRS 0 to 10 at 0 hours (at OT call time)
1.3. Vomiting (yes or no) measured at OT call time (0 hours), 6 hours, 12 hours and 24 hour postoperative
2. Capillary blood sugar measured using a capillary blood glucose monitoring device at 0 hours (at OT call time)
3. Measured using urine dipstick pre- and post-operatively:
3.1. Ketonuria: nil, 1+, 2+, 3+, 4+ at 0 hours and postoperative 6 hours
3.2. Glycosuria: nil, 1+, 2+, 3+, 4+ at 0 hours and postoperative 6 hours
4. Post-general anesthesia (GA) to intraoperative interval: blood pressure pre GA (baseline), lowest intraoperative blood pressure measured on an automated blood pressure monitoring device, medication needed to maintain blood pressure in OT prior to intubation measured using medical records
5. Usage of antiemetics measured using chart on drug dosage and number of times administered preoperative, intraoperative and postoperative
6. Post-operation time to first oral feed and first flatus measured using medical records at 0 hours, 6 hours, 12 hours, 24 hours.
7. Resting pain score measured using VNRS 0 to 10 at 0 hours, 6 hours, 12 hours and on day 1 before mobilization
8. Interval from surgery to ambulation measured using medical records
8.1. Sitting up (time 0 hours, 6 hours, 24 hours)

8.2. Walking (time 0 hours, 6 hours, 24 hours)
8.3. Passing urine for the first time after removal of catheter (time 0 hours, 6 hours, 24 hours)
9. Fever (≥38°C) measured using medical records at 0 hours, 6 hours, 12 hours and 24 hours post-operative
10. Operation to discharge interval: number of days of admission measured using medical records
11. Major complications measured using medical records at 0 hours, 6 hours and 24 hours
11.1. ICU admission: yes/no - number of days of admission
11.2. Aspiration pneumonitis: yes /no
11.3. Mallory Weiss tear: yes /no

Overall study start date
23/03/2021

Completion date
30/06/2022

Eligibility

Key inclusion criteria
1. Patients planned for elective gynecology surgery
2. Age more than 18 years old
3. Receiving general anesthesia
4. Body Mass Index (BMI) <35 kg/m²
5. ASA I-II

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
260

Key exclusion criteria
1. BMI >35 kg/m²
2. Abdominal mass >28 weeks palpable
3. Gastroesophageal reflux disease
4. H/O gastrointestinal surgery
5. Emergency gynecology surgery
6. Type 1 and type 2 diabetes mellitus
7. Psychiatric disorder (unable to give consent)
8. Anticipated ICU admission

9. Anticipated difficult Intubation
10. Suspected COVID-19 infection or COVID-19 positive

Date of first enrolment
24/05/2021

Date of final enrolment
31/05/2022

Locations

Countries of recruitment
Malaysia

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

Organisation
Pusat Perubatan Universiti Malaya

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Sponsor type
University/education

Funder(s)

Funder type
University/education

Funder Name
Pusat Perubatan Universiti Malaya

Results and Publications

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

Intention to publish date
31/12/2022

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version v1	25/03/2021	01/06/2021	No	Yes
Protocol file			01/06/2021	No	No
Protocol file	version 2		24/01/2022	No	No
Protocol file	version 3		31/01/2022	No	No