PARTICIPANT INFORMATION SHEET

Study Title:

"PREOPERATIVE FREE ACCESS TO CARBOHYDRATE DRINK AS OPPOSE TO FREE ACCESS TO WATER IN ELECTIVE GYNAECOLOGY SURGERY– RANDOMISED TRIAL"

Version No: 1

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We would like to invite you to take part in a research study. Before you decide whether to participate, you need to understand why the research is being done and what it would involve. Please take time to read the following information carefully; talk to others about the study if you wish.

Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

1.What is the purpose of this study?

The purpose of this study is to evaluate the effects of preoperative free access of water compared to free access of carbohydrate drink till Operation Theatre (OT) call time on pre-operative discomfort, satisfaction and postoperative recovery.

2.Why is this study important?

The study is important to show the difference in the outcome between both these groups to help improve our current practice in future.

3.What type of study is this?

It's a study conducted in UMMC in which patients are allocated at random (by chance alone) to receive either carbohydrate drink or water till Operation Theatre (OT) call time assessing on patients discomfort, satisfaction and recovery after operation.

4.What is the procedure that is being tested? (If applicable)

On the day of the surgery, you will be either be asked to:

A. No solid foods from midnight and to be permitted to freely drink water up to the time of OT call time

B. No solid foods from midnight and to be permitted to freely drink Carbohydrate drink up to the time of OT call

Questionnaires will be given to you pre operatively,

upon call to operating theatre and postoperative time.

5.Does the investigatory product contain cultural sensitive ingredients eg: bovine or porcine? (if applicable)

No

6.Why have I been invited to participate in this study?

You have been invited to participate in this study because the fulfilment of the inclusion criteria as below:

Recruitment: Patients planned for elective gynaecology surgery

Inclusion criteria:

- Patients planned for elective gynaecology surgery
- Age of more than 18 years olds
- Receiving general anaesthesia
- Body Mass Index (BMI) <35 kg/m2
- ASA I-II

7.Who should not participate in the study?

Exclusion criteria

- BMI > 35
- Abdominal mass > 28 weeks palpable
- Gastroesophageal reflux disease
- H/O Gastrointestinal surgery
- Emergency gynecology surgery
- Type 1 and Type 2 DM
- Psychiatric disorder (unable to give consent)
- Anticipated ICU admission
- Anticipated Difficult Intubation
- Patient who is suspected COVID 19 infection or COVID 19 positive

8.Can I refuse to take part in the study?

Yes, you are allowed to do so. You are allowed to refuse to participate and you will be given all standard care and treatment as per protocol.

9.What will happen to me if I take part?

On the day of the surgery, you will be either be asked to:

A. No solid foods from midnight and to be permitted to freely drink water up to the time of OT call time

B. No solid foods from midnight and to be permitted to freely drink Carbohydrate drink up to the time of OT call

Questionnaires will be given to you pre operatively,

upon call to operating theatre and postoperative time. You will be

observed for hydration and recovery status.

10.How long will I be involved in this study?

You will be involved in this study from 12 midnight from the day of the operation till the day and time of discharge

11.What are the possible disadvantages and risks?

Both measures taken are ideally safe – and will not harm you as the reason guidelines also indicate patients to be allowed clear fluids up to 1 hours before surgery and based on the recent study the risk of stomach content entering in to lungs is low.

They will be assessed from time to time and if required they will be started on IV 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

12.What are the possible benefits to me?

There may or may not be of any benefits to you. Information obtained from this study will help improve standard practice for preoperative oral care in all women going for elective gynaecology surgery. If proven, in future patients can be allowed to drink freely till OT call time.

13.Who will have access to my medical records and research data?

The investigator, coinvestigator and medical personals helping to collect the data will have access to your medical records and research data.

14.Will my records/data be kept confidential?

All your information obtained in this study will be kept and handled in a confidential manner, in accordance with applicable laws and/or regulations. When publishing or presenting the study results, your identity will not be revealed without your expressed consent. Individuals involved in this study and in your medical care, qualified monitors and auditors, the sponsor or its affiliates and governmental or regulatory authorities may inspect and copy your medical records, where appropriate and necessary. Data from the study will be archived and for the purpose of analysis, but your identity will not be revealed at any time.

15.What will happen to any samples I give? (If applicable)

The samples will be collected, tested then and there and the results will be noted. Ex: urine ketone dipstick, urine glucose and reflow

16.What will happen if I don't want to carry on with the study?

You may withdraw from the study at any stage of the procedure, and be rest assured that your standard care will not be affected upon your withdrawal.

17.What if relevant new information about the procedure/ drug/ intervention becomes available? (If applicable)

Yes, you will be informed if any new information relevant to intervention becomes available and you might need to re-consent if needed based on new information

18.What happens when the research study stops? (If applicable)

If the study is stopped early for any reason you will be informed and arrangements will be made for your care to be continued

19.What will happen to the results of the research study?

Results will be recorded and analyzed. It will be then presented to the research center. The results will not be shared with you.

20.Will I receive compensation for participating in this study?

No you will not receive any compensation for participating in this study as it follows standard protocol for all patients going for elective gynaecology surgery.

21.Who funds this study?

By the Department of Obstetrics and Gynaecology, University Malaya Medical Centre

22.Who should I contact if I have additional questions/problems during the course of the study?

Dr Nantharuban

Affiliation Medical Officer

Obstetrics and Gynaecology Department,

University Malaya Medical Centre

Hand phone: 017-6141621

23.Who should I contact if I am unhappy with how the study is being conducted?

Medical Research Ethics Committee

University of Malaya Medical Centre

Telephone number: 03-7949 3209/2251