

Can adding watermelon to the diet of hyperemesis gravidarum patients help to maintain their hydration status after hospital discharge and increase their body weight?

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| Submission date 19/05/2019 | Recruitment status No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 24/05/2019 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 19/06/2023 | Condition category Pregnancy and Childbirth | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol

Background and study aims

Hyperemesis Gravidarum (HG) is the severe form of nausea and vomiting in pregnancy (NVP), which affects about 0.3–3.6% of pregnant women. HG is defined as the symptom of nausea and /or vomiting during early pregnancy where there are no other causes. It affects up to 80% of pregnant women and is one of the most common indications for hospital admission in early pregnancy. Our study aims to determine that watermelon in their diet improves the recovery in HG patients by improving hydration status which is evaluated by changes in body weight after hospital discharge. This will provide scientific data to construct standard dietary advice for women with HG. This study is derived from a recently completed study in our centre and the result show watermelon is well tolerated by HG patients.

Who can participate?

Patients who are getting discharged from hospital admission for hyperemesis gravidarum.

What does the study involve?

Patients will be randomized into control and intervention group upon discharge from ward. The intervention group will be given a dietary advice leaflet, watermelon and weighing scale to bring back home and control group will receive a dietary leaflet and weighing scale. All patient will be weighed and need to answer a Simplified Nutritional Appetite Questionnaire (SNAQ) and Pregnancy-Unique Quantification of Emesis (PUQE) questionnaire. Patients are required to take watermelon before each meal or snack on whenever needed. 1 and 2 weeks after discharge, patients will be interviewed through phone calls, they required to provide body weight measurements, SNAQ and PUQE score will be reevaluated.

What are the possible benefits and risks of participating?

Benefits: patient will have weight gain by improving their appetite There is no risk factor

Where is the study run from?
University Malaya Medical Centre, Kuala Lumpur, Malaysia.

When is the study starting and how long is it expected to run for?
Patients will start to be recruited from 01/06/2019 and the study will end around 31/12/2019.

Who is funding the study?
Research committee, Department of Obstetrics and Gynaecology, University Malaya medical centre.

Who is the main contact?
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Additional identifiers**Clinical Trials Information System (CTIS)**

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

NMRR:-19-546-47548

Study information**Scientific Title**

The effect of standard dietary advice in hyperemesis gravidarum patients: a randomised prospective trial

Acronym

N/A

Study objectives

Watermelon in the diet of HG women improves body weight gain after hospital discharge

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 21/05/2019, the Medical Research Ethics Committee of University Malaya Medical Centre (Medical Research Ethics Committee, University of Malaya Medical Centre, Lembah Pantai, 59100, Kuala Lumpur, Malaysia; 03-7949 3209; umrec@um.edu.my), ref: 2019327-7262.

Study design

Prospective randomised controlled trial

Primary study design

Interventional

Study type(s)

Other

Health condition(s) or problem(s) studied

hyperemesis gravidarum

Interventions

1. All patients who are being discharged from gynaecology ward with diagnosis of hyperemesis gravidarum will be screened on the day of discharge, using the Eligibility Form and patients who fulfilled study criteria will be approached to participate.
2. All participants will be provided with patient information sheet. Participant is encouraged to ask question about the trial.
3. Written consent will be taken from all who agree to participate in this study.
4. Each participant will be interviewed by the investigator and information obtained including from clinical notes will be transcribed to the Case Report Form.
5. Randomization will be generated using random number generator at Random.org in random block of 4 or 8 by investigator who is not involved in recruitment.
6. The random allocation sequence will be placed in sealed numbered opaque envelopes for strict number order assignment to participants. Randomization is by effected opening the lowest remaining numbered sealed envelope just prior to discharge.
7. Participant will be randomized to watermelon (intervention) group or control group.
8. All participants required to measure body weight before discharge using a digital weighing scale which is provided with one layer thin clothing, empty the bladder, and remove the shoes and other accessories. Also required to complete SNAQ and PUQE form on the day of hospital discharge.
9. Each participant will be given a dietary advice leaflet recommended for HG patients and a digital weighing scale to bring home.
10. Participant who is randomized into trial group will be provided with 2 whole watermelons to be taken home. Standard preparation and storage protocol will be provided. Patient will be requested to take 1/8th of a whole watermelon (approximately 500g) in a day in separate portions before each meal for 2 weeks from hospital discharge and to snack on watermelon if desired.
11. Participants will be contacted through phone calls at 1 week and 2 weeks after discharge. They will be interviewed; required to provide body weight measurements, measured using the digital scale given following the standard protocol provided, SNAQ and PUQE score will be reevaluated.
12. Data collection by the investigator will be completed when case report forms and outcome forms are completed.

Intervention Type

Other

Primary outcome(s)

Change in body weight in 1st week and 2nd week after hospital discharge compared to body weight at discharge.

Key secondary outcome(s)

1. Poor appetite evaluated by using Simplified Nutritional Appetite Questionnaire (SNAQ) score at 1 week and 2 weeks after hospital discharge
2. Pregnancy-Unique Quantification of Emesis (PUQE) score 1 week and 2 weeks after discharge.

Completion date

31/12/2019

Eligibility

Key inclusion criteria

1. Admitted with a diagnosis of HG.
2. Confirmed clinical pregnancy (at least a positive pregnancy test if an intra-uterine gestational sac is not yet visible on ultrasound).
3. Gestation less than 16 weeks.
4. Age 18 years old and above.
5. First admission in current pregnancy for HG.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Female

Key exclusion criteria

1. Confirmed non-viable pregnancy.
2. Allergy or intolerance to watermelon.
3. Aversion to watermelon.
4. Multiple gestations.

Date of first enrolment

01/06/2019

Date of final enrolment

30/11/2019

Locations

Countries of recruitment

Malaysia

Study participating centre

university malaya medical centre

Jalan Universiti, Lembah Pantai,
Kuala Lumpur

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50603

Sponsor information

Organisation

University Malaya Medical Centre

ROR

<https://ror.org/00vkrxq08>

Funder(s)

Funder type

University/education

Funder Name

University Malaya Medical Centre

Results and Publications

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

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| Results article | | 17/06/2023 | 19/06/2023 | Yes | No |