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

Submission date
19/05/2019

Recruitment status
No longer recruiting

Registration date
24/05/2019

Overall study status
Completed

Last Edited
19/06/2023

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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?
Dr. Gayaithiri Ramasandran
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Study website
N/A

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
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other

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

Secondary outcome measures
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.

Overall study start date
01/03/2019

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

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
128

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,
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Sponsor information

Organisation
University Malaya Medical Centre

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Sponsor type
University/education

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
01/12/2020

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