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Food tasting trial in women admitted for severe nausea and vomiting of pregnancy

Submission date
15/12/2017

Recruitment status
No longer recruiting

Registration date
24/12/2017

Overall study status
Completed

Last Edited
18/01/2023

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 a fairly common condition in early pregnancy that casues a lot of nausea and vomiting that usually leads to hospitalization because women are dehydrated, starved and unable to self sustain adequate oral intake. Certain foods might provoke the vomiting and nausea and there may be certain foods that are more tolerable for women with HG. The aim of this study is to evaluate the response of women with HG to food items identified from a previous questionnaire based HG study in our centre that indicates they might represent better tolerated food. The food items to be tested in this trial, apple, watermelon, bread and crackers) are listed in order of likelihood of being better tolerated. The data obtained may provide experimental data to aid in the construction of evidence based dietary advice for women affected by HG. The aim of this study is to find the superior food item from the list of 4 in terms of tolerability and agreeability in our trial participants affected by HG.

Who can participate?
Women aged 18 and older who are admitted to in University Malaya Medical Centre, Malaysia for HG.

What does the study involve?
Each participants is required to taste and eat, in random order all the four trial food items, each of standard bite size portions in presence of the investigator and observed for 10 minutes after each food has been chewed and swallowed. Participants are asked to score the severity of their nausea using a scale before tasting, two and 10 minutes after each food items. They are required after tasting each item to record their nausea score, vomit response (if any) and the food agreeability score of the food they have just tasted. Between each test, participants rinse their mouth and have a gap of two minutes to recuperate.

What are the possible benefits and risks of participating?
There may be no immediate direct benefit but it is possible that participants may discover a food type that is suitable for them. There are no immediate risks involved except that they may feel nauseated or vomit during the food tasting.

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?
December 2017 to December 2018

Who is funding the study?
Obstetrics and Gynaecological Department of University Malaya Medical Centre (Malaysia)

Who is the main contact?
1. Dr. Tan Gi Ni (Scientific)
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2. Professor Peng Chiong Tan (Scientific)

Contact information

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Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2017106-5653

Study information

Scientific Title
Food tasting trial in women admitted for hyperemesis gravidarum

Study objectives
We postulate that apple will be best tolerated followed by watermelon, bread and crackers in women hospitalised for hyperemesis gravidarum.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Research Ethics Committee, University of Malaya Medical Centre, 31/10/2017, ref: MREC ID No: 2017106-5653

Study design
This is a single-centre trial that involves tasting of four food items given in random order to each participant with hyperemesis gravidarum

Primary study design
Interventional

Secondary study design
Randomised cross over 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
The intervention involves food tasting of four food items given in random order to each participant (within subject analysis) with hyperemesis gravidarum.

Food tasting requires ingestion of a standard bite size portion of a food item as stated below:
1. One slice of red watermelon (Weight approximately 20 grams)

2. A slice of plain white bread with the crusts cut off 1 cm within (Approximately 5 x 5 cm in size)
3. A slice of red apple, (Weight approximately: 20 grams, Fuji Apple)
4. Quarter piece of Jacobs Cream Crackers (Manufacturer: Nestle)

Participants are monitored for 10 minutes after each food item is tasted before proceed to the next food item. The order of food items tasted will be randomized in order to minimize effects from being influenced by the previous food items.

Intervention Type
Other

Primary outcome measure
1. Nausea score is measured using the visual numerical rating scale from 0 to 10 at 2 and 10 minutes of tasting each food item
2. Agreeability score on each food item tasted is measured using a visual numerical rating scale from 0 to 10 at ten minutes after each food item is ingested

Secondary outcome measures
Urges to vomit, heave or gag are measured using observations "in" 10 minutes after each food item is ingested.

Overall study start date
01/06/2017

Completion date
30/12/2018

Eligibility

Key inclusion criteria
1. Patients admitted with a presumed diagnosis of hyperemesis gravidarum
2. Confirmed clinical pregnancy (at least a positive pregnancy test if gestational sac is not yet visible on ultrasound)
3. Gestation less than 16 weeks
4. Age 18 years old and above
5. Patient is within 24 hours of first admission for hyperemesis gravidarum in the current pregnancy

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
72

Total final enrolment
72

Key exclusion criteria
1. Inability to participate or consume the food due to extreme symptoms
2. Confirmed non-viable pregnancy
3. Known taste or swallowing disorder
4. Any allergies to food items tested

Date of first enrolment
09/01/2018

Date of final enrolment
03/07/2018

Locations

Countries of recruitment
Malaysia

Study participating centre
University of Malaya Medical Centre
Lembah Pantai
Kuala Lumpur
Malaysia
59100

Sponsor information

Organisation
University of Malaya

Sponsor details
Department of Obstetrics and Gynaecology
University of Malaya Medical Center
Lembah Pantai
Kuala Lumpur
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59100

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00rzspn62

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Department of Obstetrics and Gynaecology, University of Malaya

Results and Publications

Publication and dissemination plan
Planned publication a peer reviewed journal.

Intention to publish date
31/12/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from:
Name of investigator 1: Dr. Tan Gi Ni
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Name of investigator 2: Professor Dr. Tan Peng Chiong
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IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		27/01/2021	27/01/2021	No	No
Results article		13/05/2021	18/01/2023	Yes	No