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Fluid tasting in patients with nausea and vomiting in pregnancy

Submission date
05/11/2019

Recruitment status
No longer recruiting

Registration date
05/11/2019

Overall study status
Completed

Last Edited
05/01/2021

Condition category
Pregnancy and Childbirth

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
As fluids tend to be easier to consume compared to solid food in women with nausea and vomiting of pregnancy (NVP), this study aims to evaluate the response to most common fluids tolerable to women experiencing NVP that are least likely to evoke nausea or vomiting, to obtain a scientific basis to construct dietary advice for women with NVP or hyperemesis gravidarum (HG).

Who can participate?
Pregnant women aged 18 years and above with hyperemesis gravidarum

What does the study involve?
A two-part study is proposed with an initial questionnaire comprising 13 common local beverages, with a view to selecting four of those beverages for a fluid tasting trial. Participants are required to drink four types of fluids in a random order. These fluids include water, ginger-flavoured drink, orange juice and lemon drink (water and ginger-flavored drink are compulsory, whereas orange juice and lemon drink are the two top ranking fluids based on the first part questionnaire). Fluid tasting involves swallowing 30 ml of a liquid. In the presence of the investigator, participants are required to take each drink, hold it for 3 seconds and rinse it in the mouth, then slowly swallow. This is repeated for the four fluid items in a randomly allocated order and participants are observed for 10 minutes after each fluid. Participants rinse their mouth with plain water at the end of tasting each fluid before proceeding to the next fluid. Drinking plain water at any time during the tasting is allowed as well. Participants are asked to score the severity of their nausea as a score from 0-10 before tasting (0 minutes), and 2 and 10 minutes after drinking each fluid. Participants are also monitored for their response after tasting, whether they have any urge to vomit, heave or gag in the 10 minutes after each fluid item is ingested. Participants provide an agreeability score on each fluid tasted at the end of 10 minutes on a scale from 0-10. 15. If participants are unable to tolerate the fluid or vomit during the test, they are allowed to rest first and continue the tasting later.

What are the possible benefits and risks of participating?
This study will outline a dietary/fluid intake recommendation for women experiencing nausea and vomiting in pregnancy as fluid intake is necessary during this period. It brings awareness of

the different fluids that are deemed more tolerable yet readily available to ingest. There are no risk factors.

Where is the study run from?
1. University Malaya Medical Centre (Malaysia)
2. Hospital Selayang (Malaysia)
3. Hospital Putrajaya (Malaysia)

When is the study starting and how long is it expected to run for?
October 2019 to March 2021 (updated 05/01/2021, previously: January 2020)

Who is funding the study?
University Malaya Medical Centre (Malaysia)

Who is the main contact?
Dr Sue Ee Eng
sueee@ummc.edu.my

Study website
Not available

Contact information

Type(s)
Scientific

Contact name
Dr Eng Sue Ee

Contact details
2-02, Block C, Li Villas Condominium, Jalan 16/20, Section 16
Petaling Jaya
Malaysia
46350
+60 (0)193555477
sueee@ummc.edu.my

Type(s)
Scientific

Contact name
Prof Peng Chiong Tan

Contact details
University Hospital. Jalan Universiti Lembah Pantai
Kuala Lumpur
Malaysia
50603
+60 (0)123052970
tanpengchiong@yahoo.com

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
NMRR-19-861-47251

Study information

Scientific Title
Fluid tasting trial in women admitted for hyperemesis gravidarum

Acronym
FLUTAH

Study objectives
Certain fluids are better tolerated in women with hyperemesis gravidarum (HG). The researchers expect that fluids identified as potentially best tolerated from the questionnaire will be supported by the experimental data thus providing a scientific basis to construct fluid advice in HG.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 29/04/2019, Medical Research Ethics Committee, University of Malaya Medical Centre (Medical Research Ethics Committee of University Malaya Medical Centre. Lembah Pantai, 59100 Kuala Lumpur, Malaysia; Tel: +60 (0)3 79493209; Email: umrec@um.edu.my)

Study design
Randomized clinical trial

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
Participants will be required to drink 4 types of fluids in random order. These fluids include water, ginger-flavoured drink, orange juice and lemon drink (water and ginger-flavored drink are compulsory, whereas orange juice and lemon drink are the 2 top ranking fluids based on the first part questionnaire).
1. Patient admitted to Gynecology ward UMMC with presumed diagnosis of hyperemesis gravidarum.
2. Screening of patient is done with the Eligibility Form (EF) and patients who fulfill the inclusion and exclusion criteria are approached for recruitment.
3. Patient will be provided with a Patient Information Sheet (PIS) and a verbal explanation of the study.
4. If the patient does not agree, they will be excluded from the recruitment and subsequent care will be according to standard treatment protocols.
5. Patients who agree to participate in the study will personally sign and date the Consent Form.
6. The participant will be interviewed by the investigator and Case Report Form (CRF) is filled up by the investigator.
7. Fluid tasting requires the swallowing of a liquid measured accurately with a syringe of 30 ml per serving in a standard 50ml disposable cup.
8. In the presence of the investigator, participants are required to take each drink, hold it for 3 seconds and rinse it in the mouth, then slowly swallow. This is repeated for the 4 fluid items in a randomly allocated order and observed for 10 minutes after each fluid item.
9. Participants will be required to rinse their mouth with plain water at the end of tasting each fluid item before proceeding to the next fluid item. Drinking plain water at any time during the tasting is allowed as well.
10. Participants will be asked to score the severity of their nausea in a visual numerical rating score from 0-10. This scoring will be done before tasting (0 minutes), 2 and 10 minutes after ingestion of each fluid item, timed using a stopwatch
11. Participants will also be monitored for their response after tasting, whether they have any urge to vomit, heave or gag in the 10 minutes after each fluid item is ingested.
12. Participants will be asked to provide an agreeability score on each fluid item tasted at the end of 10 minutes in a visual numerical rating score from 0-10.
13. Participants will be given an Outcome Form (OF) to answer after ingestion of each fluid item. Below are the items that participants are required to record in that form:
• Nausea score in Visual Numerical Rating Scale (NVNRS) at 0, 2 and 10 minutes
• Signs questions (S_Q) to each participant after tasting each fluid item at 10 minutes
• Agreeability score in Visual Numerical Rating Scale (AVNRS) at 10 minutes
14. Participants will be given a gap of 2 minutes in between tasting of each fluid item to fill up the Outcome Form and rinse their mouth
15. If participants are unable to tolerate the fluid item or vomit during the test, they will be allowed to rest first and continue the tasting later.
16. Data collection by the investigator will be completed when:
• Questionnaire Forms are completed by participants
• Case Report Forms are completed when participants are discharged

Intervention Type
Other

Primary outcome measure
1. Participant’s nausea score measured using a visual numerical rating scale from 0 to 10 before tasting (0 minutes), 2 and 10 minutes after tasting each fluid item
2. 'Agreeability score’ on each fluid item measured using a visual numerical rating scale from 0 to 10 at 10 minutes
3. Signs questions (S_Q) to each participant after tasting each fluid item at 10 minutes

Secondary outcome measures
Observations of each participant after tasting each fluid item, i.e. whether they have any urge to vomit, heave or gag in 10 minutes after each fluid item is ingested

Overall study start date
05/10/2019

Completion date
31/03/2021

Eligibility

Key inclusion criteria
1. Patients admitted with 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 in current pregnancy for hyperemesis gravidarum

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
72

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

Date of first enrolment
15/10/2019

Date of final enrolment
28/02/2021

Locations

Countries of recruitment
Malaysia

Study participating centre
University Malaya Medical Centre
Jalan Universiti, Lembah Pantai
Federal Territory of Kuala Lumpur
Malaysia
59100

Study participating centre
Hospital Selayang
Lebuh Raya Selayang-Kepong
Batu Caves
Malaysia
68100

Study participating centre
Hospital Putrajaya
Jalan P9, Presint 7
Federal territory Putrajaya
Malaysia
62250

Sponsor information

Organisation
University Malaya Medical Centre

Sponsor details
Department of Obstetrics and Gynecology
Jalan Universiti Lembah Pantai
Kuala Lumpur

Malaysia
50603
+60 (0)379494422
fomadmin@um.edu.my

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00vkrxq08

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Malaya Medical Centre

Results and Publications

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

Intention to publish date
30/05/2021

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