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Oral versus intravenous rehydration in management of women with morning sickness

Submission date
22/11/2020

Recruitment status
No longer recruiting

Registration date
06/12/2020

Overall study status
Completed

Last Edited
16/02/2024

Condition category
Pregnancy and Childbirth

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aim.
Hyperemesis gravidarum (HG) is a complication of pregnancy that involves severe nausea and vomiting and is one of the commonest causes for hospital admission in pregnancy. HG can also lead to dizziness, dehydration, and weight loss. Rehydration and correction of electrolyte imbalance in the blood is the goal of the management of hyperemesis. These are usually achieved using fluid supplementation intravenously (into the vein) in the hospital. Another option for rehydration therapy would be Oral Rehydration Salts (ORS) (taken by mouth), which are easily available, easily prepared, and self-administered. The aim of this study is to compare the response in terms of patient's satisfaction and ability to improve hydration with oral rehydration therapy compared to intravenous rehydration therapy.

Who can participate?
Healthy pregnant women aged 18 or over will be invited to participate in this study. Participants with a viable pregnancy, in their first trimester, first hospital admission with nausea and vomiting in pregnancy will be suitable. Pregnant women with medical problems, multiple pregnancy, or allergies to the oral rehydration salts will be excluded from the study.

What does the study involve?
Participants will be randomly allocated into two groups where one group will receive oral rehydration therapy (taken by mouth) and the other group will receive intravenous rehydration therapy (via a small plastic tube into a vein in the arm). Participants in both groups are encouraged to eat as much as tolerated. On admission, participants weight, vital signs, and baseline investigation (using a blood and urine sample) will be recorded. Vital signs and nausea experienced by participants will be recorded every 4 hours.

At the end of the 12 hours duration, urine and blood samples will be taken again, and weight will be recorded. Participant's satisfaction scores will also be obtained. If at any time the participants feel that they are unable to tolerate the oral rehydration salts, or become unwell, they will be given necessary treatment. These circumstances will be recorded.

What are the possible benefits and risks of participating?
Participants will receive the benefit of the treatment of their hyperemesis. The possible risks are low, but participants may develop allergies to the components of the oral rehydration salt.

Where is the study run from?
The Department of Obstetrics & Gynaecology, University Malaya Medical Centre (Malaysia)

When is the study starting and how long is it expected to run for?
From April 2020 to January 2023

Who is funding the study?
The Department of Obstetrics & Gynaecology, University Malaya Medical Centre (Malaysia)

Who is the main contact?
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Contact information

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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Protocol version 1.1

Study information

Scientific Title
Oral Rehydration therapy versus IntraVenous rehydration therapy in the first 12 hours following hospitalisation for hyperemesis gravidarum: a multicentre randomised controlled trial

Acronym
ORIV

Study objectives
Although intravenous (IV) rehydration is superior to oral rehydration therapy (ORT) in improving ketonuria, ORT will have greater patient satisfaction and will also result in the resolution of ketonuria in the initial management of hyperemesis gravidarum.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 07/04/2020, Medical Research Ethics Committee, of the University Malaya Medical Centre (Lembah Pantai, 59100 Kuala Lumpur, Malaysia; +60 (0)3-79493209 ext. 2251; no email contact), ref: 2020212-8283

Study design
Single-center interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Hyperemesis gravidarum

Interventions
Participants will be randomized into two arms (1:1) via labeled envelopes which will be given to the participants upon recruitment. Randomization will be generated by a random sequence generator, provided by random.org. to avoid bias.
Participants will be hospitalised and will receive either:
1. Standard intravenous rehydration (1.5L of 0.9% saline or HM solution over 12 h, run at 125 cc /h)
2. Oral rehydration therapy (diluted in 250 cc of water every 4 h) for a period of 12 h

Intervention Type
Mixed

Primary outcome measure
Current primary outcome measure as of 22/07/2021:
1. Patients satisfaction with allocated rehydration regime using VNRS scale (Visual Numerating Rating Score) from 0 to 10, with 0 being the worst score) at 12 h
2. Weight (g) measured at baseline and 12 h
3. Improvement of ketonuria measured using urine samples collected at baseline and 12 h

Previous primary outcome measure:
1. Patients satisfaction with allocated rehydration regime using VNRS scale (Visual Numerating Rating Score) from 0 to 10, with 0 being the worst score) at 12 h
2. Weight (g) measured at baseline and 12 h
3. Improvement of ketonuria measured using blood samples collected at baseline and 12 h

Secondary outcome measures
1. Hospital admission to discharge interval measured at the point of discharge
2. Nausea measured using serial nausea score at 0, 4, 8, and 12 h
3. Treatment preference measured using Likert's scale on the preference of treatment at 12 h
4. Deviation from protocol measured from investigators notes at the point of discharge
5. Hematocrit (Hct), electrolytes level measured using blood samples collected at 12 h

Overall study start date
01/04/2020

Completion date
06/01/2023

Eligibility

Key inclusion criteria
1. Aged ≥18 years
2. Confirmed pregnancy by urine pregnancy test and presence of intrauterine sac
3. Clinical diagnosis of hyperemesis gravidarum, with presence of ketonuria of at least 2+ on

admission
4. Gestation age less than 14 weeks
5. First hospital admission for hyperemesis gravidarum, and within 2 h of admission, where rehydration therapy has not formally been commenced

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
220 participants

Total final enrolment
124

Key exclusion criteria
1. Allergy to oral rehydration salts
2. Women with an underlying medical disorder (including diabetes mellitus, hypertension, heart disease, renal disease, and endocrine disorder such as hyperthyroid disorder)
3. Multiple pregnancy
4. Proven non viable pregnancy

Date of first enrolment
10/02/2021

Date of final enrolment
06/01/2023

Locations

Countries of recruitment
Malaysia

Study participating centre
University Malaya Medical Centre
Jalan Universiti
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Sponsor information

Organisation
University of Malaya Medical Centre

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Sponsor type
Hospital/treatment centre

Website
https://www.um.edu.my/

ROR
https://ror.org/00rzspn62

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University of Malaya Medical Centre

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact journal. Please use the contact details below to request a protocol.

Intention to publish date
30/01/2024

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 3	17/07/2021	06/03/2023	No	No
Results article		15/02/2024	16/02/2024	Yes	No