

Oral versus intravenous rehydration in management of women with morning sickness

Submission date 22/11/2020	Recruitment status No longer recruiting	☒ Prospectively registered ☒ Protocol
Registration date 06/12/2020	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 16/02/2024	Condition category Pregnancy and Childbirth	☐ 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?

1. Dr Maherah binti Kamarudin

maherah@ummc.edu.my

2. Dr Wan Nurul Ezyani binti Wan Jabarudin

ezyani@gmail.com

Contact information

Type(s)

Scientific

Contact name

Dr Maherah Kamarudin

Contact details

Jalan Universiti

Kuala Lumpur

Malaysia

59100

+60 127440731

maherah@ummc.edu.my

Type(s)

Public

Contact name

Dr Wan Nurul Ezyani Wan Jabarudin

Contact details

8, Jalan GP 3/4

Gombak

Malaysia

68100

+60 143384851

ezyani@gmail.com

Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

Single-center interventional randomized controlled trial

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

Female

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

Kuala Lumpur

Malaysia

59100

Sponsor information**Organisation**

University of Malaya Medical Centre

ROR

<https://ror.org/00rzspn62>

Funder(s)**Funder type**

Hospital/treatment centre

Funder Name

University of Malaya Medical Centre

Results and Publications

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?
Results article		15/02/2024	16/02/2024	Yes	No
Protocol file	version 3	17/07/2021	06/03/2023	No	No