# Delayed compared with early feeding in the initial hospital management of hyperemesis gravidarum

Submission date	Recruitment status  No longer recruiting	[X] Prospectively registered		
14/03/2016		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
16/03/2016	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
20/05/2020	Pregnancy and Childbirth			

#### Plain English summary of protocol

Background and study aims

Nausea and vomiting are common symptoms during early pregnancy, occurring in about 70–85% of pregnancies. Some pregnant women experience excessive nausea and vomiting, known as hyperemesis gravidarum, which leads to dehydration and significant weight loss. Hospitalisation is typically needed to rehydrate patients through a drip and to control nausea and vomiting with medication. In hyperemesis gravidarum, nausea may be triggered by just the thought of food, and vomiting often follows drinking or eating. In women recently hospitalised for hyperemesis it is not known whether there is benefit to a short (12 hour) delay in eating and drinking to allow rehydration and medication to take effect before eating and drinking is restarted. On the other hand, continuing to feed at the same time as rehydration and medication may permit the quickest recovery path. The aim of this study is to find out which is the better approach.

#### Who can participate?

Pregnant women aged 18 or over with hyperemesis gravidarum

#### What does the study involve?

Participants are randomly allocated to one of two groups. One group is encouraged eat and drink as soon as possible after hospitalisation. The other group is told to delay eating and drinking (fast) for the first 12 hours after hospitalisation, then resume eating and drinking at their own pace. Both groups receive intravenous rehydration (a drip), thiamine (vitamin) supplementation and anti-emetic (anti-vomiting) medication as standard inpatient treatment for hyperemesis gravidarum. Frequency of vomiting, nausea, patient satisfaction and duration of hospitalisation are measured.

What are the possible benefits and risks of participating?

We do not foresee any major benefits or significant risks. It is not clear which intervention will prove to be superior and there is a distinct likelihood the interventions may produce similar outcomes.

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? April 2016 to September 2017

Who is funding the study? University of Malaya (Malaysia)

Who is the main contact? Prof. Peng Chiong Tan pctan@um.edu.my

#### Contact information

#### Type(s)

Public

#### Contact name

Prof Peng Chiong Tan

#### Contact details

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### Additional identifiers

Protocol serial number

1206.12

## Study information

#### Scientific Title

Delayed compared with early oral intake in the initial manangement of hyperemesis gravidarum: a randomised trial

#### **Study objectives**

An initial 12-hour period of fasting (delayed oral intake) at hospitalisation for hyperemesis gravidarum to allow for hydration and anti-emetic medication to become effective compared to early feeding will result in less nausea and vomiting and higher patient satisfaction at 24 hours.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

University Malaya Medical Centre Medical Ethics Committee, 04/02/2016, approval no. 1206.12

#### Study design

Two-arm clinical trial

#### Primary study design

Interventional

#### Study type(s)

Treatment

#### Health condition(s) or problem(s) studied

Hyperemesis gravidarum

#### **Interventions**

Participants are randomized to:

1. Delayed oral intake (fasting) for the first 12 hours after hospitalisation for hyperemesis gravidarum followed by resumption of taking fluids and solids orally at the participants own pace 2. Encouraged to take fluids and solids orally as soon as, as much as and as often as tolerated after hospitalisation for hyperemesis gravidarum

Both arms are to receive intravenous rehydration, oral thiamine supplementation and intravenous anti-emetic as standard inpatient treatment for hyperemesis gravidarum

#### Intervention Type

Behavioural

#### Primary outcome(s)

- 1. Frequency of vomiting in the first 24 hours
- 2. Nausea score (using a Visual Numerical Rating Scale from 0 to 10) at enrollment, 8, 16 and 24 hours
- 3. Patient's satisfaction score (using a Visual Numerical Rating Scale from 0 to 10) at 24 hours

#### Key secondary outcome(s))

- 1. Duration of hospitalisation
- 2. Ketonuria at 24 hours
- 3. An 8-item symptoms questionnaire at 24 hours
- 4. Participant preference on feeding regimen in a future hospitalisation for hyperemesis gravidarum at 24 hours
- 5. Participant recommendation of their feeding regimen to a friend in the same circumstances at 24 hours

#### Completion date

30/09/2017

# **Eligibility**

#### Key inclusion criteria

- 1. Clinical diagnosis of hyperemesis gravidarum
- 2. First hospitalisation for hyperemesis gravidarum in current pregnancy
- 3. Presence of ketonuria by urine dipstick (of 2+ or greater) at hospitalisation
- 4. At least 18 years of age
- 5. Pregnancy gestation of 14 weeks or less

#### Participant type(s)

**Patient** 

#### Healthy volunteers allowed

No

#### Age group

Adult

#### Lower age limit

18 years

#### Sex

Female

#### Total final enrolment

160

#### Key exclusion criteria

- 1. Multiple pregnancy
- 2. Molar pregnancy
- 3. Confirmed non-viable pregnancy
- 4. Any medical condition that contraindicates oral feeding or fasting

#### Date of first enrolment

01/04/2016

#### Date of final enrolment

30/09/2017

#### Locations

#### Countries of recruitment

Malaysia

# Study participating centre University Malaya Medical Centre

Jalan Universiti Kuala Lumpur Malaysia 50603

# Sponsor information

#### Organisation

University of Malaya (Malaysia)

#### **ROR**

https://ror.org/00rzspn62

# Funder(s)

#### Funder type

University/education

#### **Funder Name**

Universiti Malaya

#### Alternative Name(s)

University of Malaya, University Malaya, Malayan University, King Edward VII College of Medicine, Raffles College, University of Malaya in Singapore, , , , UM

#### **Funding Body Type**

Government organisation

#### **Funding Body Subtype**

Universities (academic only)

#### Location

Malaysia

#### **Results and Publications**

Individual participant data (IPD) sharing plan

#### IPD sharing plan summary

Not expected to be made available

#### **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	30/04/2020	20/05/2020	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes