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

Submission date
14/03/2016

Recruitment status
No longer recruiting

Registration date
16/03/2016

Overall study status
Completed

Last Edited
20/05/2020

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
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?
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Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use then contact details below to request a patient information sheet

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 measure
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

Secondary outcome measures
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

Overall study start date
01/04/2016

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

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
160

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)

Sponsor details
Lembah Pantai
Kuala Lumpur
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Sponsor type
University/education

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, UM

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Malaysia

Results and Publications

Publication and dissemination plan
We plan to publish the trial results. We are not planning to release raw trial data.

Intention to publish date
30/09/2018

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