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Dextrose saline versus saline solution infused for the initial rehydration of hyperemesis gravidarum

Submission date
26/04/2012

Recruitment status
No longer recruiting

Registration date
16/05/2012

Overall study status
Completed

Last Edited
30/11/2015

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Hyperemesis gravidarum (HG) is severe nausea and vomiting occurring during pregnancy. It is fairly common, affecting about 2% of pregnant women, and hospital admission is needed for treatment. HG can lead to dehydration and starvation. The main treatment for HG is intravenous rehydration (fluids given directly into a vein through a drip). It is not known which fluid is best for the initial treatment of HG. Normal saline solution contains salt in the same concentration as blood. Dextrose-saline solution in addition to salt also contains dextrose (a form of sugar). Dextrose will provide calories at a time when the patient is not likely to be drinking or eating properly yet due to HG, which may allow a quicker recovery from starvation. The amount of glucose that we intend to administer over the 24-hour study period is probably about half of the carbohydrate intake in an average woman's diet when she is eating normally. We are investigating whether the addition of dextrose to the intravenous solution used to treat women at the point of their hospitalisation for HG will result in a quicker recovery from starvation and make the patient feel better faster.

Who can take part?
Women aged 18 and over, hospitalised for the first time in their current pregnancy due to uncomplicated HG, and no more than 16 weeks pregnant.

What does the study involve?
Participants are randomly allocated to receive either normal saline solution or dextrose-saline solution.

What are the possible benefits and risks of participating?
In HG patients with severe thiamine deficiency (which can occur after prolonged starvation), dextrose infusion can cause a condition called Wernicke's encephalopathy. To prevent this, before starting rehydration, all participants will receive a multivitamin intravenous injection containing thiamine.

Where is the study run from?
University Malaya Medical Centre, Kuala Lumpur, Malaysia.

When is the study starting and how long is it expected to run for?
November 2010 to February 2012.

Who is funding the study?
University Malaya Medical Centre, Kuala Lumpur, Malaysia.

Who is the main contact?
Prof P C Tan

Contact information

Type(s)
Scientific

Contact name
Prof Peng Chiong Tan

Contact details
University of Malaya
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50603

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
811.8

Study information

Scientific Title
Dextrose saline versus saline solution infused for the initial rehydration of hyperemesis gravidarum: a randomized trial

Acronym
DexSal Trial

Study objectives

Rehydration with the intravenous infusion of 5% dextrose-0.9% saline is hypothesised to result in a quicker resolution of ketonuria and generate a higher level of perceived well being compared to 0.9% saline.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University Malaya Medical Centre Ethics Committee, 22/09/2010, ref: 811.8

Study design
Double-blind randomised intervention 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 below to request a patient information sheet

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

Interventions
Three litres of 5% dextrose-0.9% saline or three litres of 0.9% saline solution infused intravenously over 24 hours.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
5% dextrose, 0.9% saline

Primary outcome measure
1. Resolution of ketonuria at 24 hours (using urine dipstick)
2. Well being at 24 hours using a Visual Numerical Rating scale (VNRS)

Secondary outcome measures

1. Correction of hyponatraemia (≥ 136 mmol/l)
2. Correction of hypochloraemia (≥ 100 mmol/l)
3. Hyperglycaemia (any glucose level ≥ 8 mmol/l)
4. Nausea score at enrollment, 8. 16 and 24 hours (using VNRS)
5. Duration of intravenous (i.v.) rehydration during hospitalisation
6. Doses of of i.v. anti-emetic
7. Admission to discharge interval

Overall study start date
09/11/2010

Completion date
09/02/2012

Eligibility

Key inclusion criteria
1. Clinical hyperemesis gravidarum with dehydration
2. Age ≥ 18 years
3. Pregnancy less than 16 weeks of gestation
4. A positive urine pregnancy test if pregnancy not confirmed by ultrasound
5. Urine ketone at least 1+ on admission
6. First admission for hyperemesis gravidarum in current pregnancy
7. Venous plasma glucose ≤ 6 mmol/l
8. Venous sodium ≥ 125 mmol/l

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
At least 200 women

Key exclusion criteria
1. Molar pregnancy
2. Women with underlying medical problem eg established gestational hypertension, diabetes, heart disease, renal disease, thyroid disorder
3. Suspected gastrointestinal causes of nausea and vomiting e.g. gastritis, gastroenteritis, peptic ulcer
4. Established non viable pregnancy
5. Preexisting medical condition that can cause or exarcebate nausea and vomiting (eg culture proven symptomatic urinary tract infection, dengue fever)

Date of first enrolment
09/11/2010

Date of final enrolment
09/02/2012

Locations

Countries of recruitment
Malaysia

Study participating centre
University of Malaya
Kuala Lumpur
Malaysia
50603

Sponsor information

Organisation
University of Malaya (Malyasia)

Sponsor details
Department of Obstetrics and Gynaecology
Faculty of Medicine
Lembah Pantai
Kuala Lumpur
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50603

Sponsor type
University/education

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

ROR
https://ror.org/00rzspn62

Funder(s)

Funder type
University/education

Funder Name
Department of Obstetrics and Gynaecology, University of Malaya (Malyasia)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2013		Yes	No