

Randomised trial of rapid outpatient rehydration versus hospital admission for hyperemesis gravidarum

Submission date 18/03/2008	Recruitment status Stopped	<input type="checkbox"/> Prospectively registered
Registration date 30/06/2008	Overall study status Stopped	<input type="checkbox"/> Protocol
Last Edited 21/02/2014	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Cecilia Bottomley

Contact details
Academic Department of Obstetrics and Gynaecology
3rd Floor Lanesborough Wing
St George's University of London
Cranmer Terrace
London
United Kingdom
SW17 0QT
ceciliabottomley@doctors.org.uk

Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title

Study objectives

Vomiting is a common symptom of early pregnancy, affecting approximately 52% of women. Hyperemesis gravidarum, or severe protracted vomiting appearing for the first time before the 20th week of pregnancy that is not associated with other coincidental conditions and is of such severity as to require the patients' admission to hospital, affects only 0.3 - 1.5% of pregnancies.

HG is associated with a decrease in ability to perform household activities, decreased interaction with existing children, decreased healthcare involvement and increased time off work. There is no consensus in the management and treatment of HG. The majority of the therapeutic anti-emetic treatment is empirical. Intravenous rehydration, correction of electrolyte imbalance, vitamin supplementation and anti-emetics remain the mainstay of treatment of severe disease.

Women with hyperemesis gravidarum (HG) who have been unable to manage with anti-emetics alone and who need rehydration have conventionally been admitted as inpatients. Rapid rehydration within a gynaecology outpatient setting has potential advantages in terms of healthcare cost and maintaining the woman within her home and family environment. Some hospitals currently operate a policy of outpatient ('day case') intravenous rehydration for HG. To date no randomised studies have been conducted comparing outpatient management for rehydration with conventional inpatient treatment.

The aim of this study is therefore to assess the success of outpatient management versus inpatient management in patients with HG.

Study hypothesis:

Rapid outpatient rehydration is as effective as inpatient admission for the treatment for hyperemesis gravidarum.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the Royal Mardsen Research Ethics Committee on the 24th April 2007 (ref: 07/Q0806/2).

Study design

Multicentre randomised controlled trial.

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Hyperemesis gravidarum

Interventions

Comparison of conventional inpatient continuous intravenous rehydration for women with HG with daily attendance at the Acute Gynaecology Unit for rehydration over four hours. The same

anti-emetic and vitamin supplementation will be given to both groups. Women are randomised by computer generated allocation.

All women will be given a single intravenous dose of cyclizine at first attendance followed by regular buccal prochlorperazine 3 mg (increased to 6 mg if ineffective). In addition, when tolerating oral input, all participants will be given oral thiamine 50 mg three times daily and folic acid 5 mg once daily. A single dose of intravenous ranitidine 50 mg will be administered to women reporting epigastric discomfort, followed by 150 mg orally twice daily. Both groups will receive intravenous fluids. The inpatient group will receive 4 litres normal saline over the first 24 hours followed by 3 litres per 24 hours. The outpatient group will receive 2 litres per day, each administered over 4 hours.

Treatment in both groups will continue until:

1. There is no ketonuria, and
2. The woman is able to tolerate food and drink, and
3. There has been no vomiting for at least 12 hours

For both groups, follow up 7 days after completion of treatment will be carried out by telephone to ascertain whether they are still using anti-emetics and whether they have had any re-admissions.

Updated 21/02/2014: The trial did not start as the clinical fellow left the position and there was no funding to support a further research post at the time.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Cyclizine, prochlorperazine, thiamine, folic acid, ranitidine

Primary outcome(s)

A difference between the two groups in reduction in Pregnancy-Unique Quantification of Emesis (PUQE) score at 48 hours.

Key secondary outcome(s)

A difference between the two groups in:

1. Number of days intravenous fluid treatment needed
2. Number with ketonuria at 48 hours
3. Improvement, at two and seven days from start of treatment, in:
 - 3.1. PUQE
 - 3.2. Drinking and eating scores
 - 3.3. Well-being rating
4. Weight change at seven days
5. Number still taking anti-emetics at one week following discharge
6. Re-attendance episodes for hyperemesis in the seven days following discharge
7. Costs of treatment

Completion date

01/04/2009

Reason abandoned (if study stopped)

Lack of funding/sponsorship

Eligibility

Key inclusion criteria

All pregnant women up to 20 weeks gestation referred to the Acute Gynaecology Unit with persistent vomiting and at least 1+ ketonuria.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

1. Women greater than 20 weeks gestation
2. Women with another medical condition manifesting as nausea and vomiting such as urinary tract infection (UTI)
3. Type 1 or 2 diabetes
4. Potassium less than 3.2 mmol/l
5. Sodium less than 130 mmol/l
6. Abnormal liver function tests (associated with increased severity of HG)
7. Abnormal thyroid function tests (associated with increased severity of HG)

Date of first enrolment

17/03/2008

Date of final enrolment

01/04/2009

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Academic Department of Obstetrics and Gynaecology
London
United Kingdom
SW17 0QT

Sponsor information

Organisation

St George's Healthcare NHS Trust (UK)

ROR

<https://ror.org/039zedc16>

Funder(s)

Funder type

Government

Funder Name

St George's Department of Obstetrics and Gynaecology Discretionary Fund (UK)

Funder Name

St George's Healthcare NHS Trust (UK) - The Directorate of Women's Health

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration