

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

<b>Submission date</b> 18/03/2008	<b>Recruitment status</b> Stopped	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 30/06/2008	<b>Overall study status</b> Stopped	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 21/02/2014	<b>Condition category</b> Pregnancy and Childbirth	<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](mailto:ceciliabottomley@doctors.org.uk)

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

### 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**

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 measure**

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

## **Secondary outcome measures**

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

## **Overall study start date**

17/03/2008

## **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

## **Age group**

Adult

## **Sex**

Female

## **Target number of participants**

100 (50 in each arm of trial)

## **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**

England

United Kingdom

**Study participating centre**

Academic Department of Obstetrics and Gynaecology

London

United Kingdom

SW17 0QT

## **Sponsor information**

**Organisation**

St George's Healthcare NHS Trust (UK)

**Sponsor details**

Blackshaw Road

London

England

United Kingdom

SW17 0RE

tom.bourne@stgeorges.nhs.uk

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.stgeorges.nhs.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**

**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