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

Submission date 18/03/2008	**Recruitment status** Stopped	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 30/06/2008	**Overall study status** Stopped	
Last Edited 21/02/2014	**Condition category** Pregnancy and Childbirth	

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

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