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Hyperemesis In Pregnancy (HIP) Trial: Inpatient versus outpatient management of severe nausea and vomiting in pregnancy

Submission date
10/03/2014

Recruitment status
No longer recruiting

Registration date
04/04/2014

Overall study status
Completed

Last Edited
15/02/2018

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
Most women will experience some degree of nausea and vomiting during the early stages of pregnancy. This is sometimes referred to as morning sickness and it usually resolves by around 20 weeks. Some experience a very severe form of nausea and vomiting which causes such dehydration that admission to hospital for fluid replacement via a drip is required. This condition is called hyperemesis gravidarum (HG). Women who experience HG often spend long periods of time in hospital. The condition is associated with a decrease in ability to perform household activities, decreased interaction with their children and increased time off work. Women with HG have significantly higher rates of depression and anxiety when compared to other pregnant women. Traditionally the treatment for HG involves admission to hospital for fluid and vitamin replacement through a drip together with anti-sickness medications. Many women find it very hard and distressing to be away from their families and normal activities of daily living. A few hospitals are now offering an outpatient service for women suffering with HG. This means that women who would normally be admitted have their treatment over a shorter period of time then go home and return the next day to receive the same rehydration and anti-sickness therapy that they would have if they were admitted to the hospital. This continues on a daily basis until the womans condition has improved and she is discharged from the service. This form of management has advantages for the woman, allowing her to remain at home, and also economic benefits for the health service, reducing the number of admissions. Outpatient management of HG is not regularly available and it is not known if it is as effective in treating the condition as the traditional inpatient treatment. This study will directly compare the two forms of management to establish if there are any differences in their effectiveness.

Who can participate?
Women with a diagnosis of HG will be asked to participate in the study when they visit the hospital for the first time.

What does the study involve?
Participants will be randomly allocated to either being admitted and treated in the traditional way or receiving their treatment as an outpatient. The outpatient approach will mean they

receive a more rapid form of rehydration therapy then go home and return the next day. The women will be followed closely and information gathered about their condition each day. A specific scoring system will be used to assess the level of sickness and vomiting. The aim of treatment is to reduce this score. Women will also be asked to complete eating, drinking and wellbeing scoring systems to assess their overall condition and these will be used to compare the two different treatments. The researchers will look at how long women need treatment for and how many of them re-attend the hospital after being discharged. The information gathered about women receiving both forms of treatment will be used to directly compare traditional inpatient management with outpatient treatment.

What are the possible benefits and risks of participating?
If outpatient management is found to be equally effective in managing women with HG it can be developed and recommended as best practice with social and economic benefits. The researchers are experienced clinical professionals working in the field of early pregnancy. They have designed and set up the outpatient management of HG service at Chelsea and Westminster Hospital, UK. There are no risks related to participation in this study.

Where is the study run from?
Chelsea and Westminster Hospital (UK)

When is the study starting and how long is it expected to run for?
The study started in March 2014. Recruitment is likely to continue for the next 2 and a half years.

Who is funding the study?
Chelsea and Westminster Hospital (UK)

Who is the main contact?
Miss Nicola Mitchell-Jones
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Contact information

Type(s)
Scientific

Contact name
Miss Nicola Mitchell-Jones

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

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

Acronym
HIP

Study objectives
Rapid outpatient rehydration is as effective as hospital admission for management of hyperemesis gravidarum.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Humber Bridge REC, December 2013, REC ref: 13/YH/0424þ

Study design
Multi-centre non-blinded randomised control 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 to request a patient information sheet

Health condition(s) or problem(s) studied
Hyperemesis gravidarum (severe nausea and vomiting of pregnancy)

Interventions

Outpatient management: Rapid outpatient rehydration
Inpatient management: Standard care

Women will be recruited and randomised to either inpatient or outpatient management. Both groups will be managed according to specific treatment protocols. On a daily basis during treatment information will be gathered from all participants. This will include; PUQE score (a validated scoring system used to assess symptoms of nausea and vomiting in pregnancy), eating and drinking score, wellbeing score, weight and blood test results. Treatment will continue for as long as it is clinically indicated. Women will be followed up at 7 days following discharge and the same information recorded. The number of repeat attendances and admissions will also be recorded.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Reduction in Pregnancy Unique Emesis Score (PUQE score) at 48 hours

Secondary outcome measures
1. Number of days intravenous fluid treatment needed
2. Number with ketonuria at 48 hours
3. Improvement, at 2 and 7 days from start of treatment, in:
3.1. Pregnancy-unique quantification of emesis and nausea (PUQE) score
3.2. Drinking and eating scores
3.3. Wellbeing rating
4. Weight change at 7 days
5. Number still taking antiemetics 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
01/03/2014

Completion date
01/09/2016

Eligibility

Key inclusion criteria
Pregnant women up to 20 weeks gestation with symptoms of hyperemesis gravidarum and at least 1+ ketonuria on dipstick

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
120 across all sites

Key exclusion criteria
1. Women greater than 20 weeks gestation
2. Women with another medical condition manifesting as nausea and vomiting such as UTI
3. Type 1 or 2 diabetes
4. Potassium < 3.2 mmol/l
5. Sodium < 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
01/03/2014

Date of final enrolment
01/02/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Chelsea and Westminster Hospital
London
United Kingdom
SW10 9NH

Sponsor information

Organisation
Chelsea and Westminster NHS Trust (UK)

Sponsor details
Research and Development Department
Unit 101, Harbour Yard, Chelsea Harbour
London

England
United Kingdom
SW10 0XD

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/02gd18467

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Chelsea and Westminster Hospital NHS Foundation Trust

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The results will be published by November 2017.

Intention to publish date
01/11/2017

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publically available repository (http://datadryad.org; DOI: doi:10.5061/dryad.c3g48).

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	05/12/2017		Yes	No
HRA research summary			28/06/2023	No	No