

Hyperemesis in Pregnancy study

Submission date 30/05/2006	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 11/07/2006	Overall study status Completed	☐ Protocol
Last Edited 28/10/2016	Condition category Pregnancy and Childbirth	☐ Statistical analysis plan
		☒ Results
		☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Study information

Scientific Title

Hyperemesis in Pregnancy study

Acronym

HiPs

Study objectives

Nausea and vomiting in pregnancy (NVP) is a frequently occurring, often debilitating condition. The impact on the mother's quality of life can be substantial. Management of NVP remains controversial and inconsistent. Out-patient rapid re-hydration may reduce the need for recurrent admission.

Our hypothesis is that outpatient management with rapid re-hydration in mothers referred to hospital with NVP does not increase readmission rate as compared to mothers receiving conventional inpatient management.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Newcastle and North Tyneside Local Research Ethics Committees, 25/02/2004, Ref: 2003/207

Primary study design

Interventional

Study design

Randomised controlled trial, participants allocated via a University web-based randomisation service

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Hyperemesis gravidarum / severe nausea and vomiting in pregnancy

Interventions

On admission, all women will be offered an anti-emetic injection (cyclizine lactate, 50 mg), and given an advice leaflet detailing helpful measures to reduce symptoms. They will be given a study information sheet and if they consent to participate they will be randomised using a web-based electronic system into one of two arms. All women will be asked to complete an initial questionnaire and a seven day self-completion questionnaire.

Intervention: women will remain in the assessment unit. After establishment of intravenous access and measurement of electrolytes, they will receive three litres of intravenous ringer lactate solution infused over six hours. During this time they will be given a leaflet explaining about NVP and self-help information to try and reduce recurrence of symptoms. After hydration women will be discharged on a seven day course of oral anti-emetics, (cyclizine lactate 50 mg) with clear instructions about contacting the assessment unit if symptoms recur or deteriorate. Women are then telephoned by a specialist midwife on day three and day seven to assess symptoms and provide support. Should a woman experience deterioration in symptoms, despite self-help and support, one further attempt at symptom control with rapid hydration and anti-emetics will be offered within seven days of the first admission.

Control: women will be admitted to the antenatal ward and managed according to current guidelines which includes intravenous therapy as prescribed. At discharge women will be given a seven day supply of oral anti-emetics and will receive a telephone call from the research midwife to encourage return of the self completion questionnaire.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Cyclizine lactate, ringer lactate solution

Primary outcome(s)

Whether rapid rehydration administered over six hours in a day care setting, combined with out-patient psychological support reduces in-patient stay and improves women's quality of life.

Key secondary outcome(s)

The cost consequences of rapid rehydration on an out-patient basis compared to the current policy of routine admission.

Completion date

31/12/2006

Eligibility**Key inclusion criteria**

Any woman attending the maternity assessment unit under 20 weeks gestation suffering from moderate or severe nausea and vomiting

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

1. Poor/no English
2. Over 20 weeks gestation
3. Under 16 year old or over 45 years
4. No treatment warranted
5. Women with significant medical conditions, e.g., insulin-dependent diabetes mellitus (IDDM), renal disease, cardiac disease
6. Women not suitable for out-patient management
7. Three admissions or more in the same week

Date of first enrolment

01/03/2004

Date of final enrolment

31/12/2006

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

School of Surgery and Reproductive Sciences

Newcastle upon Tyne

United Kingdom

NE1 7RU

Sponsor information

Organisation

Newcastle upon Tyne Hospitals NHS Trust (UK)

ROR

<https://ror.org/05p40t847>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

WTE research midwife, jointly funded by the hospital Trust and the University of Newcastle.

Funder Name

Consumables supplied by the hospital.

Results and Publications

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	01/05/2016		Yes	No