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Hyperemesis in Pregnancy study

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

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

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

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
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.

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

Overall study start date
01/03/2004

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

Age group
Adult

Sex
Female

Target number of participants
50

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
England

United Kingdom

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)

Sponsor details
Royal Victoria Infirmary
Queen Victoria Road
Newcastle upon Tyne
England

United Kingdom
NE1 4LP

Sponsor type
Hospital/treatment centre

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

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2016		Yes	No