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Day care versus Inpatient Management of nausea and vomiting of pregnancy - D.I.M. trial

Submission date	Recruitment status	[X] Prospectively registered
03/11/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
10/11/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
10/09/2014	Pregnancy and Childbirth	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00795561

Secondary identifying numbers

N/A

Study information

Scientific Title
Randomised controlled trial of day care versus inpatient management of nausea and vomiting of pregnancy

Acronym
D.I.M. trial

Study objectives
Up to 80% of all pregnant women experience some form of nausea and vomiting during their pregnancy. The International Statistical Classification of Disease and Related Health Problems ICD-10 defines hyperemesis gravidarum (HG) as persistent and excessive vomiting starting before the end of the 22nd week of gestation, and further subdivides the condition into mild and severe, severe being associated with metabolic disturbances such as carbohydrate depletion, dehydration or electrolyte imbalance. HG is a diagnosis of exclusion, characterised by prolonged and severe nausea and vomiting, dehydration, large ketonuria and >5% bodyweight loss.

We aim to conduct a prospective open label randomised controlled trial to test the hypothesis that the availability of day care services for the initial treatment of nausea and vomiting of pregnancy (NVP) reduces the mean duration of stay in hospital by 1 day (28.6%) and results in significantly greater patient satisfaction compared with standard inpatient management.

The null hypothesis states there is no difference in the amount of inpatient hospital days when women with NVP are treated initially in day care or by standard inpatient admission.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Clinical Research Ethics Committee of the Cork Teaching Hospitals, 03/09/2008, ref: ECM 5 [5] 02 /09/09

Study design
Open-label single-centre 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
Nausea and vomiting of pregnancy (NVP)/ hyperemesis gravidarum (HG)

Interventions
Day care treatment vs inpatient treatment of NVP. Patients will attend Cork University Maternity Hospital for day care or inpatient treatment until resolution of symptoms.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Number of inpatient nights spent in hospital, secondary to NVP from initial presentation until 22 weeks gestation. An inpatient night will be defined as requiring an inpatient bed between the hours of 20.00 and 08.00.

Secondary outcome measures
1. Total number of hours spent in hospital, secondary to NVP from initial presentation until 22 weeks gestation
2. Total amount of intravenous fluids administered, secondary to NVP from initial presentation until 22 weeks gestation
3. Total amount of anti-emetics administered, secondary to NVP from initial presentation until 22 weeks gestation
4. Total multivitamin complexes administered, secondary to NVP from initial presentation until 22 weeks gestation
5. Patient satisfaction recorded after the first day care/ inpatient treatment. Patient satisfaction will be measured by the Client Satisfaction Questionnaire (CSQ-18B). To avoid bias, this questionnaire will be recorded only once after the first day care/ inpatient treatment. If a participant receives more than one treatment she will not be asked to fill in the questionnaire again. The first presentation for day care/inpatient treatment may range from conception to 22 weeks gestation.
6. Incidence of miscarriage
7. Infant birth weight at delivery
8. Gestational age at delivery
9. Total days lost at work due to NVP, asked at 16 weeks gestation

Overall study start date
05/01/2009

Completion date
01/05/2009

Eligibility

Key inclusion criteria
All pregnant women under 22 weeks gestation presenting to the emergency department of Cork University Maternity Hospital (CUMH) are candidates for inclusion in the trial. Patients who fulfil the International Classification Disease (ICD-10) definition of hyperemesis gravidarum (mild and severe) will be enrolled in the study.

Women (no age limits) will be admitted to the study if they have two or more of the following criteria:
1. Ongoing viable intrauterine pregnancy/ pregnancies <22 weeks gestation
2. Persistent vomiting (>3 episodes/ 24 hours) not attributable to other causes
3. Severe nausea not attributable to other causes
4. Dehydration diagnosed by the presence of ketonuria
5. Electrolyte imbalance not attributable to other causes

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
124

Key exclusion criteria
Women will not be admitted to the study if any of the following criteria are present:
1. Women with a confirmed urinary tract infection (mid stream urine isolation of a single strain of uropathogen >10^5 bacteria/ml)
2. Women with molar pregnancies
3. Women with non-viable pregnancies
4. Women who have already received treatment for NVP outside of this trial
5. Pregnant women who present who will not be booking at CUMH for their pregnancy or are not resident in the South West of Ireland i.e. day care treatment is not an option
6. Women who do not have a good understanding of English

Date of first enrolment
05/01/2009

Date of final enrolment
01/05/2009

Locations

Countries of recruitment
Ireland

Study participating centre

Anu Research Centre
Cork
Ireland
-

Sponsor information

Organisation
Cork University Maternity Hospital (Ireland)

Sponsor details
Wilton
Cork
Ireland
-
+353 (0)21 4920500
obs.gyn@ucc.ie

Sponsor type
Hospital/treatment centre

Website
http://www.ucc.ie/en/obsgyn

ROR
https://ror.org/04q107642

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Cork University Maternity Hospital (Ireland)

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	01/10/2014		Yes	No