

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

<b>Submission date</b> 03/11/2008	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
<b>Registration date</b> 10/11/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 10/09/2014	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof John R Higgins

**Contact details**  
Anu Research Centre  
Department of Obstetrics and Gynecology  
University College Cork  
Cork University Maternity Hospital  
Wilton  
Cork  
Ireland  
-  
J.Higgins@ucc.ie

## Additional identifiers

**ClinicalTrials.gov (NCT)**  
NCT00795561

**Protocol serial number**  
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

**Study type(s)**

Treatment

**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(s)**

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.

**Key secondary outcome(s)**

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

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

Female

**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)

**ROR**

<https://ror.org/04q107642>

# Funder(s)

## Funder type

Hospital/treatment centre

## Funder Name

Cork University Maternity Hospital (Ireland)

# 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?
<a href="#">Results article</a>	results	01/10/2014		Yes	No