

Olanzapine (ZYPREXA) versus Haloperidol (Novo-Peridol) for the relief of Nausea and Vomiting (N&V) in patients with advanced cancer

Submission date 07/06/2005	Recruitment status Stopped	☐ Prospectively registered ☐ Protocol
Registration date 23/06/2005	Overall study status Stopped	☐ Statistical analysis plan ☐ Results
Last Edited 01/02/2019	Condition category Signs and Symptoms	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

ClinicalTrials.gov (NCT)

NCT00124930

Protocol serial number

MCT-71119

Study information

Scientific Title

A randomised double-blind, parallel-group study comparing Olanzapine (ZYPREXA) with Haloperidol (Novo-Peridol) for the relief of Nausea and Vomiting (N&V) in patients with advanced cancer

Acronym

OHN - 1

Study objectives

The objective of this study is to compare the efficacy and safety of haloperidol and olanzapine in the control of chronic nausea in patients with advanced cancer who have failed first line anti-emetic therapy with metoclopramide or domperidone.

Please note that as of 28/01/2008 this trial record was updated. All updates to this trial record have been performed under the date 28/01/2008 in the relevant section of the trial record. Please also note that as of 2006 the contact and sponsor of this trial also changed. The previous contact for scientific queries was Dr Jose Pereira, and the previous sponsor was the University of Calgary (Canada).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Health Research Ethics Board, University of Calgary, Calgary, Alberta (Canada) approved on the 31st May 2005 (ref: # 18371)

Primary study design

Interventional

Study design

Multicentre two arm randomised parallel trial using placebo, with study participant, study investigator, and caregiver blinding

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Nausea in patients with advanced cancer

Interventions

1. Olanzapine (Zyprexa)
2. Haldol (haloperidol)

Added as of 28/01/2008:

Both patients and investigators will be blinded as to which medication the patients will be receiving. Medications will be inserted in opaque capsules to ensure blinding.

Added as of 22/08/2008:

This trial was stopped early due to poor recruitment. The actual end date of this trial was 30/06/2008, and the previous anticipated end date was 31/12/2008.

Contact for public queries:

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Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Olanzapine (ZYPREXA), Haloperidol (Novo-Peridol)

Primary outcome(s)

Severity of nausea on days 3 and 5 as determined by patient self-report Edmonton Symptom Assessment Scale (ESAS) (Visual Analogue Scale).

Key secondary outcome(s)

1. Treatment satisfaction as assessed by patients (daily)
2. Frequency of adverse events caused by olanzapine and haloperidol as indicated by the Adverse Events Questionnaire
3. Spontaneous report of adverse events by patients and the modified St Hans Rating Scale (daily)
4. Changes in appetite
5. Depression
6. Anxiety as assessed by the ESAS
7. Changes in quality of life parameters as assessed by the Functional Assessment of Cancer Therapy - General (FACT-G) (days 3 and 5)

Completion date

30/06/2008

Reason abandoned (if study stopped)

Poor recruitment

Eligibility

Key inclusion criteria

Current inclusion criteria as of 28/01/2008:

1. Male or female 18 years or older

2. Significant nausea or vomiting
3. An expressed need for nausea or vomiting to be relieved with medication
4. Patient has failed a prior trial with metoclopramide or domperidone
5. Attempts at addressing probable and possible underlying causes of nausea have been attempted and failed
6. Sufficient cognitive function
7. Ability to communicate well with the study personnel and comply with the requirements of the study
8. Willingness to give written informed consent
9. Able to take oral medications
10. Life expectancy estimated to be greater than 2 weeks

Previous inclusion criteria:

1. Male or female 18 years or older
2. Significant nausea or vomiting
3. An expressed need for nausea or vomiting to be relieved with medication
4. Patient has failed a prior trial with metoclopramide or domperidone
5. Attempts at addressing probable and possible underlying causes of nausea have been attempted and failed
6. Sufficient cognitive function
7. Ability to communicate well with the study personnel and comply with the requirements of the study
8. Willingness to give written informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

Current exclusion criteria as of 28/01/2008:

1. Has partial or complete bowel obstruction
2. Currently taking haloperidol or olanzapine
3. Has drug-induced extrapyramidal side effects (as identified by the screening and/or baseline examinations and Modified St. Hans Rating Scale)
4. Has a known hypersensitivity to haloperidol or olanzapine
5. Has documented Parkinson's disease
6. Is undergoing chemotherapy or radiation therapy that includes abdomen, brain, oesophagus or stomach in its field
7. Has experienced extrapyramidal syndromes (EPS) or intolerance in the past to olanzapine or haloperidol

8. Concurrently receiving or has received in the last 28 days an investigational drug
9. Has previously participated in this trial

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Date of first enrolment

13/06/2005

Date of final enrolment

30/06/2008

Locations

Countries of recruitment

Canada

Study participating centre

BCCA - Centre for the Southern Interior

Kelowna, British Columbia

Canada

V1Y 5L3

Sponsor information

Organisation

University of British Columbia (Canada)

ROR

<https://ror.org/03rmrcq20>

Funder(s)

Funder type

Research organisation

Funder Name

Canadian Institutes of Health Research (CIHR) (Canada) - <http://www.cihr-irsc.gc.ca> (ref: MCT-71119)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration