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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

Registration date
23/06/2005

Last Edited
01/02/2019

Recruitment status
Stopped

Overall study status
Stopped

Condition category
Signs and Symptoms

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] 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
Dr Gillian Mary Fyles

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00124930

Secondary identifying numbers
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)

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

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

Secondary outcome measures
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)

Overall study start date
13/06/2005

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
80

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
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Sponsor information

Organisation
University of British Columbia (Canada)

Sponsor details
305-2075 Wesbrook Mall
Vancouver, British Columbia
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Sponsor type
University/education

Website
http://www.ubc.ca/

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

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