Early recognition and optimal treatment of delirium in patients with advanced cancer

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Miscellaneous and site unspecified neoplasms benign
Study type	Interventional

Summary

ID

NL-OMON39561

Source
ToetsingOnline

Brief title
RCT Delirium in cancer patients

Condition

- Miscellaneous and site unspecified neoplasms benign
- Deliria (incl confusion)

Synonym
confusion, delirium

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: subsidie ZonMW,sponsorgelden voor

palliatieve zorg

Intervention

Keyword: delirium, palliative care, recognition, treatment.

Outcome measures

Primary outcome

Primary endpoint for this trial is a DRS-R-98 severity rating score < 15,25 and

a decline > 4.5 points on the total scale.

Secondary outcome

Secondary endpoint is the amount of time elapsed between start of treatment and

diminishing of the signs of delirium. (DOS < 3, DSR-R-98 < 15,25)

Study description

Background summary

Delirium is a disorder of consciousness, attention and cognition and, as such, a neuropsychiatric
complication that occurs frequently in patients with advanced cancer. Delirium has a negative influence
on quality of life and on the ability for communication in a crucial phase of illness for patients and their
families. Variable presentation of symptoms hinders recognition of delirium significantly and therefore
patients are often being undertreated. Based on limited evidence the preferred drug to treat delirium is
haloperidol. Improvement of recognition and treatment options for delirium are warranted.

Study objective

In this study, we aim to improve recognition of delirium in a palliative care population with advanced
cancer and we aim to provide evidence for optimal treatment of delirium through adequate dosing of
preferred neuroleptic.

Primary objectives:
1) To validate the Delirium Observation Screening Scale in patients with advanced cancer.
2) To compare the efficacy of olanzapine treatment with haloperidol treatment (standard care) in a randomised clinical trial with regard to reversibility and time to recovery.

Secondary objective:
1) To determine delirium recall and delirium-related distress in patients with advanced cancer and their primary caregivers.

Study design

To address the aforementioned objectives we designed a randomised clinical trial for patients with advanced cancer who are admitted to the medical oncology ward or hospice.

Intervention

On admission to the medical oncology ward or hospice, all patients with advanced cancer will be asked to participate in this study. Consenting patients will be submitted to delirium observation screening according to Delirium Observation Screening scale (DOS). Subsequently DOS screening will be performed twice weekly until discharge. Each patient who*s score is > 3 (DOS positive) is showing significant symptoms of delirium and will be submitted to the revised Delirium Rating Scale (DRS-R-98) to confirm diagnosis. To test validity of the DOS scale for this particular population, each DOS positive score will be randomly matched with a patient with a DOS score < 3 (DOS negative) and this patient will also be submitted to DRS-R-98. When diagnosis of delirium is confirmed by DRS-98, patients will be randomised between treatment of delirium with olanzapine or haloperidol (usual care). Treatment in both groups will consist of identification and management of underlying aetiologies of delirium if possible and adding neuroleptic medication for symptom control. Patients who recover from their delirium episode as well as their caregivers will be asked to complete the Delirium Experience Questionnaire (DEQ) to assess recall of the delirium experience and the degree of distress related to the delirium episode.

Study burden and risks

Considering the fact that both medications are accepted medications for treatment of delirium participating patients will not run unforeseen risks other than the known side effects associated with these medications.
The nature of the burden associated with participation will mostly be limited to interventions that are part of usual care in diagnosing and treating of delirium. The extent of additional burden consists of short 10 minute interviews with an independent assessor on day 1,2,3,4,7 and 14. On recovery

of delirium the trial will end and the patient will be asked to fill out a 10 minute questionnaire on delirium recall.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

* Patient has been diagnosed with advanced cancer;
* Age * 18;
* Patient or his / her significant other speaks Dutch fluently.

Exclusion criteria

* Delirium is due to alcohol withdrawal;
* Patient has been diagnosed with glaucoma, Parkinson*s disease or dementia;
* Patient is being treated with other neuroleptic medication or lithium (except for low dose neuroleptics used in the treatment of neuropathic pain);
* Patient has another psychiatric disorder that is considered (by investigator) to interfere with assessment of delirium;
* Patient had a QTc-interval of > 500 msec on ECG made on admission;
* Patient has a history of neuroleptic malignant syndrome;
* Patient has a history of convulsions.

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2010
Enrollment:	200
Type:	Actual

Medical products/devices used

Product type:	Medicine
Generic name:	olanzapine
Registration:	Yes - NL outside intended use
Product type:	Medicine
Brand name:	Haldol
Generic name:	haloperidol

Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	17-07-2009
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	07-10-2009
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-11-2010
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	08-12-2010
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-05-2011
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-09-2011
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-09-2011
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-04-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Approved WMO Date:	26-04-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-05-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-03-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	09-04-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	30-07-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-09-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2009-013403-55-NL
CCMO	NL28610.029.09