Early Recognition and Optimal Treatment of Delirium in Patients with Advanced Cancer.

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Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21878

Bron
NTR

Aandoening

advanced cancer, delirium

Ondersteuning

Primaire sponsor: VU University Medical Center
Overige ondersteuning: ZonMw

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Primary endpoint for this trial is a DRS-R-98 severity rating score < 15,2518, as this is a measure for establishing clearance of delirium.

Toelichting onderzoek

Achtergrond van het onderzoek

We designed a randomised clinical trial for patients with advanced cancer who are admitted to our medical oncology ward. On admission to the medical oncology ward, all patients with advanced cancer will be asked to participate in this study. Consenting patients will be submitted to delirium observation screening according to the 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.

Doel van het onderzoek

The hypothesis to be tested is that by consequent screening and subsequent treatment with optimized treatment strategies of patients with advanced cancer the quality of life and their communication with family can be improved. In addition, we hypothesize that delirium is reversed in < 50% of advanced cancer patients diagnosed with delirium by current haloperidol treatment and that treatment of delirium with olanzapine will have a significantly better outcome.

Onderzoeksopzet

At entry: Within 24 hours after admission DOS score, diagnostic tests.

Subsequently, patients undergo cognitive screening with DOS twice weekly and at any time the onset of delirium is suspected. When screening with DOS results in a score ≥ 3, patient will be submitted to DRS-R-98 by independent assessor as soon as possible on the same day.

Effects and side effects of treatment will be measured by submitting enrolled patients to DOS and DRS-R-98 as mentioned above and to the 3rd version of the Common Terminology Criteria of Adverse Events (CTCAE)41 before start of treatment and subsequently on day 2, 4, 7, and 14 after start of treatment.

Treatment duration will be determined by the clinical benefit the patient experiences due to the study drug and therefore will be variable.

Evaluable patients will have been treated until clearance of the delirium signs, until death or for a minimum of one week before deciding on irreversibility of the delirium signs.

Onderzoeksproduct en/of interventie

On admission to the medical oncology ward all patients with advanced cancer will be asked to participate in this study. Consenting patients will be submitted to delirium observation screening according to the DOS and risk and predisposing factors for development of delirium will be recorded (see appendix Risk/DOS). Subsequently DOS screening will be performed twice weekly until discharge or when otherwise indicated by patients' physician or nurse. Each patient with a DOS-score > 3 (DOS positive) is suspected of a delirium and will be submitted to the revised Delirium Rating Scale (DRS-R-98) by an independent assessor to confirm diagnosis. Together with each DOS positive patient, a DOS-negative patient (having a DOS score < 3) in up to 100 consecutive patients will also be submitted to DRS-R-98 by an independent assessor. The independent assessor is blinded with regard to the DOS score of a patient. This allows us to assess the performance of DOS relative to the gold standard DRS-R-9818. When DRS-R-98 total score is ≥ 17,75 diagnosis of delirium is confirmed. (see appendix Flow sheet study design)
When diagnosis for delirium is confirmed by DRS-R-98 (DRS-R-98 total score is ≥ 17,75), treatment of all patients will consist of identification and management of underlying aetiologies of delirium if possible and adding neuroleptic medication for symptom control. Patients will be randomly assigned to a treatment group of haloperidol (usual care) or olanzapine. (see appendix Flow sheet study design).

Treatment with olanzapine will be started with an initial dose of 2,5 – 5 mg orally or intramuscularly, after 2 hours subsequent titration of dosage will be based on clinical judgement with a maximum of 20 mg per 24 hours divided over a maximum of 3 gifts7. Sustenance dose will consist of half of the total titrated dose per 24 hours in one gift. Treatment with haloperidol will be administered according to the national palliative care guideline for delirium40. Haloperidol dosing will be titrated, with repeated dosing of 0,5 - 2mg orally or subcutaneously every 40 minutes until signs of delirium diminish, with a maximum of 20 mg orally or 10 mg subcutaneously per 24 hours. Sustenance dose will consist of half of the total titrated dose per 24 hours in one or two gifts. Reversibility of delirium and time to recovery will be assessed by submitting the patients to DOS on a daily basis and to DRS-R-98 by an independent assessor on day 2, 3, 4 and 7 during the first week of treatment. The independent assessor is blinded with regard to the medication given. During the second week of treatment, DOS will be done twice weekly and DRS-R-98 will be done when DOS score is < 3 and on day 14 (end of study). Delirium is considered cleared when DRS-R-98 severity score is < 15,2518.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patient has been diagnosed with advanced cancer;

2. Age ≥ 18;

3. Patient or his / her significant other speaks Dutch fluently.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Delirium is due to alcohol withdrawal;

2. Patient has been diagnosed with glaucoma, Parkinson’s disease or dementia;

3. Patient is being treated with other neuroleptic medication or lithium;

4. Patient has another psychiatric disorder that is considered (by investigator) to interfere with
assessment of delirium;

5. Patient had a QTc-interval of > 480 msec on ECG made on admission;

6. Patient has a history of neuroleptic malignant syndrome;

7. Patient has a history of convulsions.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-09-2009
Aantal proefpersonen:	300
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	07-10-2010
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2289
NTR-old	NTR2559
Ander register	:
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A