Quality of life and Paracetamol In advanced Dementia

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Regularly scheduled administration of paracetamol, compared to placebo, leads to better quality of life, daily functioning, mood, and less pain, care dependency, behavioural problems and psychotrophic medication use.

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

Samenvatting

ID

NL-OMON24190

Bron
NTR

Verkorte titel
Q-PID study

Aandoening

Advanced dementia, Quality of Life, Paracetamol, long-term care facility

Gevorderde dementie, Kwaliteit van leven, Paracetamol, verpleeghuis

Ondersteuning

Primaire sponsor: Leiden University Medical Center (LUMC)
Overige ondersteuning: ZonMW
Bestemmingsfonds Verpleeghuisgeneeskunde (HGOG)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Quality of life: QUALIDEM, DS-DAT

Toelichting onderzoek

Achtergrond van het onderzoek

Undiagnosed and untreated pain is a serious and frequent problem in persons with advanced dementia, leading to behavioural problems. Although pain is difficult to assess in persons with advanced dementia, the impact on quality of life (QoL) is believed to be huge. In addition, recent studies suggest that pain also has a negative impact on the course of activities of daily living (ADL) function. Until now, there are no proven effective interventions on QoL in persons with dementia in a long-term care facility. However, several interventions are effective in diminishing mediators of QoL (challenging behaviour, depressed mood, sleeping disorders), including pharmacological treatment of pain. Social participation can also be seen as an indication for QoL, and has been shown to benefit from administration of paracetamol. However, so far no intervention studies are available that investigated the effects of pain management on QoL in advanced dementia directly.

The overall aim of this study is to achieve optimal QoL and ADL function in long term care facility (LTCF) residents with moderate to (very) severe dementia and moderate to low QoL, and to achieve less care dependency through pain treatment with paracetamol

Doel van het onderzoek

Regularly scheduled administration of paracetamol, compared to placebo, leads to better quality of life, daily functioning, mood, and less pain, care dependency, behavioural problems and psychotrophic medication use.

Onderzoeksopzet

T0: Screening for in - and exclusion criteria: Demographic data (age, gender), dementia severity (Reisberg GDS), comorbidity (FCI), Quality of life (QUALIDEM, DS-DAT)

After being enrolled, measurements in week 1, 6, 7 and 12 (starting and ending points of study medication periods):

Quality of life (QUALIDEM, DS-DAT), Neuropsychiatric symptoms (NPI-NH), ADL functioning (Katz-15), Care dependency (CDS), Pain (MOBID-2), medication use

Onderzoeksproduct en/of interventie

Subjects will receive either orally administered paracetamol at a maximum dose of 3 grams

(3 x 2 tablets of 500 mg each) daily for 4 weeks, followed by 2 weeks 2.5 grams, according to recent protocols of chronic use of paracetamol in older people, or placebo tablets. A six week administration period of corresponding placebo (or vice versa) follows, separated by a washout period of 7 days. The placebo tablets will resemble the paracetamol tablets in colour, taste and composition.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Diagnosis of dementia, Reisberg Global Deterioration Scale 5-7 Age 65 years or older QUALIDEM (Quality of life) score below the expected median score of 70) Not using any pain medication one week before start study. Residents with PRN prescribed paracetamol ("as needed") are also eligible, if the use of paracetamol in the last week was not more than 1 gram/day and less than 3 grams/week

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Presence of a severe psychiatric disorder, Severe liver insufficiency/disease, Use of >4 units alcohol per day, Allergy to study drugs, Concomitant use of flucloxacillin, carbamazepine, fenytoïne, fenobarbital, isoniazide and/or rifampicine, Weight < 50 kg

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-01-2018
Aantal proefpersonen:	95
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	20-10-2017
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	NL6592
NTR-old	NTR6766
Ander register	CCMO : ABR registration number: NL60476.058.17.

Resultaten