Quality of life and Paracetamol In advanced Dementia

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24190

Source
NTR

Brief title
Q-PID study

Health condition

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

Gevorderde dementie, Kwaliteit van leven, Paracetamol, verpleeghuis

Sponsors and support

Primary sponsor: Leiden University Medical Center (LUMC)
Source(s) of monetary or material Support: ZonMW
Bestemmingsfonds Verpleeghuisgeneeskunde (HGOG)

Intervention

Outcome measures

Primary outcome

Quality of life: QUALIDEM, DS-DAT

Secondary outcome

Neuropsychiatric symptoms of dementia (NPI-NH)

ADL functioning (Katz-15)

Care dependency (CDS)

Pain (MOBID-2)

Medication use

Study description

Background summary

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

Study objective

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.

Study design

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

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2018
Enrollment:	95
Type:	Anticipated

Ethics review

Positive opinion

Date:	20-10-2017
Application type:	First submission

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
NTR-new	NL6592
NTR-old	NTR6766
Other	CCMO : ABR registration number: NL60476.058.17.

Study results