Paracetamol to enhance quality of life and daily function and to decrease care dependency in advanced dementia: A randomized, double-blind, placebo-controlled crossover trial in long-term care facilities.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Dementia and amnestic conditions
Study type	Interventional

Summary

ID

NL-OMON47642

Source
ToetsingOnline

Brief title
Quality of life and Paracetamol In advanced Dementia (Q-PID trial)

Condition

- Dementia and amnestic conditions

Synonym
Dementia

Research involving

Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: ZonMW;ministerie van VWS

Intervention

Keyword: Dementia, Long term care facility, Paracetamol, Quality of life

Outcome measures

Primary outcome

The difference between baseline QoL and follow-up scores (QUALIDEM and DS-DAT).

Secondary outcome

Neuropsychiatric symptoms (NeuroPsychiatric Inventory-Nursing Homes)

ADL (Katz-15)

Care dependency (Care Dependency Scale)

Dementia severity (Reisberg Global Deterioration Scale)

Pain (MOBID-2 pain scale)

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 living in long-term care facilities. 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.

Study objective

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

We will:
1. evaluate the effect of regularly scheduled administration of paracetamol on QoL ;
2. evaluate the effect of paracetamol on ADL function and care dependency;
3. evaluate the effect of paracetamol on pain, change in challenging behaviour and (antipsychotic) medication use.

Study design

A randomized, double-blind, placebo-controlled cross-over trial.

Intervention

Orally administered paracetamol at a dose of 3 grams a day the first 4 weeks (3x2 tablets of 500mg), followed by 2 weeks 2x2 +1x1 tablets a day) or corresponding placebo. Two treatment periods of six weeks, separated by a washout period of 7 days.

Study burden and risks

Older persons with dementia have a high probability of experiencing negative consequences of pain, such as behavioral problems (agitation, apathy), reduced functioning, sleep problems and depression. A recently executed randomized controlled trial showed that good pain treatment in persons with dementia reduced agitation, regardless of having any visible pain. Since paracetamol is known for its analgesic effect, paracetamol can reduce the negative consequences of pain, and thus the quality of life in persons with dementia.

The negative consequences for the participants (bitter taste of the tablets, swallowing more tablets per day) will not outweigh the benefits mentioned above. Side-effects could be (rarely): headache or allergy. In case of chronic use of paracetamol (months to years) in a dosage above the recommended maximum (3-4 gram daily): liver damage, kidney damage, blood abnormalities. A safety

monitoring committee will be installed which will guard trial quality and anticipate on serious adverse events.
This study will not interfere with standard care, diagnostics and treatment for persons with dementia.

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

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 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
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-01-2018
Enrollment:	95
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Paracetamol
Generic name:	Paracetamol
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	10-10-2017
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	27-11-2017
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	19-04-2018
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	24-07-2018
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	15-11-2018
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	EUCTR2017-000039-16-NL
CCMO	NL60476.058.17