The effect of chlorhexidine on the incidence of aspiration pneumonia in care home residents: design of a double-blind cluster randomized placebo-controlled trial.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28334

Source
NTR

Health condition

Oral health care, chlorhexidine, aspiration pneumonia, dysphagia, care home

Sponsors and support

Primary sponsor: Department of Dentistry, Radboud University Nijmegen Medical Centre, Nijmegen, The Netherlands
Source(s) of monetary or material Support: Sponsor request (pending): Dentaid benelux bv

Intervention

Outcome measures

Primary outcome

To assess the influence of the addition of rinsing with a 0.05% chlorhexidine-containing solution to usual daily oral hygiene care on the incidence of pneumonia in physically-impaired care home residents with dysphagia.

Secondary outcome

To assess the correlation between some medical, physical, and oral conditions (age, gender, diseases diagnosed, care dependency, medication use, number of teeth and implants present, and presence of removable dentures) and the incidence of aspiration pneumonia in physically-impaired, older care home residents with dysphagia who rinse with a 0.05% chlorhexidine-containing solution or a placebo in addition to usual daily oral hygiene care.

Study description

Background summary

Background:

Pneumonia is an important cause of death in care home residents. Dysphagia and bad oral health are significant risk factors for developing aspiration pneumonia. Oral hygiene care reduces the number of oral bacteria and the risk of aspiration pneumonia, however, it is not yet clear which oral hygiene care intervention is most efficacious in reducing the risk of aspiration pneumonia.
The aim of the study is to assess whether the application of a 0.05% chlorhexidine-containing solution in addition to usual daily oral hygiene care reduces the incidence of pneumonia in physically-disabled care home residents with dysphagia.

Methods/design:

The study is designed as a double-blind cluster randomized placebo-controlled trial, with care home wards as units of randomization. The randomization will be balanced for dysphagia severity and care dependency. During one year, 500 physically-disabled care home residents with dysphagia will be followed. The intervention consists of applying a 0.05% chlorhexidine-containing solution twice daily immediately after the usual oral hygiene care, whereas the control group receives a placebo. The application method of the 0.05% chlorhexidine-containing solution, rinsing the solution or cleaning the oral cavity with a gauze containing 0.05% chlorhexidine-containing solution, is depending on the severity of the dysphagia.
Other research data which will be gathered are: age, gender, diseases diagnosed, dysphagia severity, care dependency, medications used actually, number of teeth and implants present, and presence of removable dentures. The study outcome is the incidence of pneumonia diagnosed by a physician, using a set of strictly described criteria. The effect of the intervention on the incidence of pneumonia will be determined using Cox regression analysis.

Discussion:

Using cluster randomization may result in random effect and cluster selection bias. Therefore, randomization will be balanced for dysphagia severity and care dependency. Furthermore, a frailty model will be included in the Cox regression analysis to take into account the clustering of data within care home wards.

Study objective

The scientific hypothesis of the present study is that oral hygiene care with a 0.05 % chlorhexidine-containing solution, compared to oral hygiene care with a placebo, reduces the incidence of pneumonia in physically-impaired care home residents with dysphagia.

Study design

1. Dysphagia Outcome and Severity Scale (DOSS): baseline and endpoint;

2. Care Dependency Scale (CDS): baseline and endpoint;

3. Patient record: Gender, age (baseline)
Diagnoses and medication use (baseline and endpoint);

4. Oral examination:Number of teeth , implants and the presence of removable dentures (baseline);

5. Pneumonia: Pneumonia will be diagnosed by a set of strictly described criteria: When symptoms occur during study.

Intervention

The intervention consists of the addition of rinsing with a 0.05% chlorhexidine-containing solution twice daily immediately after the usual oral hygiene care. The execution of the intervention is depending on the severity of the dysphagia. The intervention for residents with dysphagia who tolerate thin liquids consists of a 0.05% chlorhexidine-containing oral rinse. The residents have to rinse for 30 seconds twice a day after the usual oral health care.

The intervention for residents with severe dysphagia who cannot tolerate thin liquids consists of additional cleaning the teeth, the gums, the tongue, the palate, and the buccal mucosa with a gauze containing 0.05% chlorhexidine-containing twice daily.

The intervention consists of applying a 0.05% chlorhexidine-containing solution twice daily immediately after the usual oral hygiene care, whereas the control group receives a placebo.

The application method of the 0.05% chlorhexidine-containing solution, rinsing the solution or cleaning the oral cavity with a gauze containing 0.05% chlorhexidine-containing solution, is depending on the severity of the dysphagia.

Contacts

Public
Department of Neurohabilitation
HAN University of Applied Sciences Nijmegen
Postbus 6960
Vanessa Hollaar
Nijmegen 6503 GL
The Netherlands
+31 (0)24 3616365
Scientific
Department of Neurohabilitation
HAN University of Applied Sciences Nijmegen
Postbus 6960
Vanessa Hollaar
Nijmegen 6503 GL
The Netherlands
+31 (0)24 3616365

Eligibility criteria

Inclusion criteria

Residents:

1. Aged 65 years or older;

2. Physically impaired;

3. Dysphagia diagnosed using the DSS by a speech therapist.

Exclusion criteria

Residents:

1. Cognitively impaired;

2. In coma or vegetative state;

3. Terminally ill;

4. Dependent on mechanical ventilation;

5. In day-care or in short-term care;

6. Slready using an oral rinse.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	14-02-2013
Enrollment:	500
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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	NL3367
NTR-old	NTR3515
Other	:
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A