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

Published: 27-08-2013
Last updated: 26-04-2024

Primary objective: 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...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Respiratory tract infections
Study type	Interventional

Summary

ID

NL-OMON39960

Source
ToetsingOnline

Brief title
Effect of 0.05% chlorhexidine solution on incidence of aspiration pneumonia

Condition

- Respiratory tract infections
- Age related factors

Synonym
aspiration pneumonia

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universiteit Nijmegen
Source(s) of monetary or material Support: Ministerie van OC&W,Er is op dit moment nog niet bekend welke fabrikant het spoelmiddel levert voor het onderzoek

Intervention

Keyword: aspiration pneumonia, care home, chlorhexidine, Oral health care

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

-

Study description

Background summary

In care homes pneumonia is the second most common infection, after urinary tract infections, and the leading cause of death from infection (Pace and McCullough, 2010). In care homes, the incidence of pneumonia is ten times higher than the incidence in the community (Oh et al, 2004). Care home residents have a higher risk of developing aspiration pneumonia than community-dwelling older people (Shariatzadeh et al, 2006).
Care home residents are often dependent on nurses for daily oral hygiene care. It has been found that care home residents have poor oral hygiene, both for teeth and removable dentures (De Visschere et al, 2006). The accumulation of oral plaque emerges and inadequate oral hygiene care increases colonization of respiratory pathogens in oral plaque (Scannapieco, 1999). Not the type of oral

bacteria, but the amount of bacteria aspirated is an important factor in the development of pneumonia (Ingles et al, 1993). Oral hygiene care, such as tooth brushing after each meal, cleaning dentures once daily and professional oral health care once weekly reduces the number of oral bacteria (Yoneyama et al, 2002; Bassim et al, 2008; Ishikawa et al, 2008). However, it is not clear which oral health care intervention is most efficacious in reducing the risk of aspiration pneumonia.

The mechanism of aspiration pneumonia onset is unknown. Scannapieco (1999) described four feasible mechanisms for oral bacteria causing respiratory infections. Colonization of pulmonary pathogens in the oral biofilm and aspiration of these pathogens into the lungs, is the first mechanism. The second mechanism is that in saliva present periodontal-disease-associated enzymes may modify mucosal surfaces and facilitate the adherence of respiratory pathogens which can be aspirated into the lungs. The third mechanism is periodontal-disease-associated enzymes destroying protective salivary pellicles. Fourth, cytokines from infected periodontal tissues may alter respiratory epithelium, which results in respiratory pathogen colonization and an increased risk of infection. However, until now no evidence for one of these hypotheses has been found. The difference in diagnosing an aspiration pneumonia or a pneumonia is clinically not possible. Therefore the diagnose pneumonia will be used.

Recently, the literature published between January 2000 and April 2009 was systematically reviewed on the risk factors of aspiration pneumonia in frail older people (van der Maarel-Wierink et al, 2011a). The following risk factors could be identified: age, male gender, lung diseases, dysphagia, diabetes mellitus, severe dementia, ACE DD genotype, bad oral health, malnutrition, Parkinson*s disease and the use of antipsychotic drugs and proton pump inhibitors. The presence of two or more of the risk factors could be an indicator that specific preventive oral health care is needed (van der Maarel-Wierink et al, 2011a). A combination of frequent toothbrushing and a pharmacological intervention, such as the use of an antiseptic mouthwash, was suggested as an adequate intervention (van der Maarel-Wierink et al, 2012).

A meta-analysis confirmed dysphagia being a significant risk factor for aspiration pneumonia in frail older people (OR = 9.84; 95% CI = 4.15 - 23.33), specifically in stroke patients: OR = 12.93; 95% CI = 8.61-19.44 (van der Maarel-Wierink et al, 2011b). Data from another study demonstrated that completely dependent residents had a 42 times and to a great extent dependent residents a 13 times higher risk of subjective dysphagia than independent residents (van der Maarel-Wierink et al, 2012).

Although oral hygiene care is known to prevent aspiration pneumonia, it is not yet clear which oral hygiene care intervention is most efficacious in reducing the risk of aspiration pneumonia (van der Maarel-Wierink et al, 2011b). The combination of usual oral hygiene care and a pharmacological intervention, using a chlorhexidine-containing solution, might be an adequate method. Twice-daily oropharyngeal cleansing with a 0.2% chlorhexidine gluconate solution has proven to reduce the risk of nosocomial pneumonia in patients residing at intensive care units, not specifically older patients (Panchabhai

et al, 2009).
A randomized controlled trial is needed to find out whether oral hygiene care with a chlorhexidine-containing solution in addition to usual oral hygiene care reduces the incidence of pneumonia in physically-impaired care home residents with dysphagia.

Study objective

Primary objective:
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 objective:
To assess the correlation between some medical, physical, and oral conditions 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.

The primary and secondary objective of the study are expressed by 2 research questions:
1) Is there any statistically significant difference with regard to the incidence of pneumonia in physically-impaired care home residents with dysphagia, who in addition to usual daily oral hygiene care rinse with a 0.05% chlorhexidine-containing solution or a placebo?

2) Is there any statistically significant correlation between on the one hand age, gender, diseases diagnosed, care dependency, medication use, number of teeth and implants present, and presence of removable dentures and on the other hand the incidence of pneumonia in physically-impaired 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 design

The study design is a randomized controlled trial, with care home wards as units of randomization. Care home wards will randomly be allocated to either the intervention group or the control group, while the groups will be balanced for dysphagia severity and care dependency. Care home residents fulfilling the inclusion criteria as well as participating physicians, speech therapists, oral health care providers, nurses, examiner and assistant examiners will be blinded to the assignment in order to prevent bias. The applied solutions will be labelled using encrypted codes which refer to the chlorhexidine-containing solution or the placebo. To prevent bias, the placebo will have the same wrapping, colour, odour, and taste as the chlorhexidine-containing solution.

Intervention

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 placebo has the same wrapping, colour, odour, and taste, and contains the same ingredients as the chlorhexidine-containing solution, except the chlorhexidine.

The application method of the 0.05% chlorhexidine-containing solution is depending on the severity of the dysphagia. Residents who tolerate thin liquids have to rinse with the 0.05% chlorhexidine-containing solution for 30 seconds twice daily immediately after the usual oral hygiene care. Residents with severe dysphagia who cannot tolerate thin liquids have to clean their teeth, gums, tongue, palate, and buccal mucosa with a gauze containing 0.05% chlorhexidine-containing solution twice daily immediately after the usual oral hygiene care.

Study burden and risks

Rinsing with a chlorhexidine-containing solution gives very rarely allergic and/or hypersensitivity reactions. Other side effects are discoloration of teeth, removable dentures, mucosa or tongue, temporary taste disorder, swelling of salivary glands, and pain. However, these are side-effects of 0.2% chlorhexidine-containing solutions and rarely of lower-concentration chlorhexidine-containing solutions, whereas the concentration used in this study is 0.05%. The (reversible) tooth and removable denture discoloration is stronger in the presence of tannins in the mouth, such as after drinking tea, coffee or wine. Oral ingestion of chlorhexidine is usually well tolerated because of the negligible systemic absorption.
The benefit for the residents in the intervention group may be a better oral hygiene status and oral health condition, and consequently, a reduction of the incidence of pneumonia. No strenuous physical examinations will be carried out and participating residents have to provide informed consent. When the symptoms of pneumonia occur, the resident will be physically examined by a physician. Only a short oral examination by an oral health care provider and determining dysphagia by a speech therapist will be carried out.

Contacts

Public
Radboud Universiteit Nijmegen

Philips van Leydenlaan 25
Nijmegen 6525 EX

NL
Scientific
Radboud Universiteit Nijmegen

Philips van Leydenlaan 25
Nijmegen 6525 EX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

aged 65 years or older
physically impaired
dysphagia diagnosed using the FOIS by a speech therapist

Exclusion criteria

-cognitively impaired (suffering from dementia)
-in coma or vegetative state
-terminally ill
-dependent on mechanical ventilation
-in day-care or in short-term care
-already using an oral rinse

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-09-2013
Enrollment:	500
Type:	Actual

Ethics review

Approved WMO Date:	27-08-2013
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	10-06-2014
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
CCMO	NL41990.091.12
Other	TC3515