A randomized controlled trial on the effect of pre-thickened oral nutritional supplements on nutritional status of nursing home residents with oropharyngeal dysphagia and (at risk of) malnutrition

Published: 04-07-2019
Last updated: 12-04-2024

The aim of this study is to determine whether the daily use of thickened oral nutritional supplements has an effect on the weight of nursing home residents with dysphagia and (risk for) malnutrition.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON48281

Source
ToetsingOnline

Brief title
DYNAMO

Condition

- Other condition
- Appetite and general nutritional disorders

Synonym
undernourishment and swallowing disorder

Health condition

dysfagie

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W,Danone Nutricia Research,Nutricia

Intervention

Keyword: dysphagia, malnutrition, nursing home residents, oral nutritional supplementation

Outcome measures

Primary outcome

Change in body weight : kg.

Secondary outcome

* Nutritional intake: macro- and micronutrients intake, fluid intake

* Compliance of the study product : % of amount of daily advice of study

product

* General and dysphagia-specific Quality of Life : EQ-5D, Dysphagia Severity

Scale, Dysphagia Quality of Life, Dysphagia Swallowing Anxiety

Study description

Background summary

Malnutrition is a common problem among nursing home residents, especially in residents with dysphagia. Malnutrition may result in detrimental health status and may impede in activities of daily living. In addition, dysphagia can lead to pneumonia or dehydration. To date, there are no studies available that have investigated the effectiveness of pre-thickened ONS on nutritional status in

dysphagic people with or at risk for malnourishment. The current study aims at investigating the effectiveness of a pre-thickened ONS range on top of standard nutritional- and dysphagia management on nutritional status in nursing home residents with dysphagia and (risk for) malnourishment.

Study objective

The aim of this study is to determine whether the daily use of thickened oral nutritional supplements has an effect on the weight of nursing home residents with dysphagia and (risk for) malnutrition.

Study design

randomized, controlled, open label- trial

Intervention

pre-thickened oral nutritional supplement

Study burden and risks

For the design of the current study, the guidelines on malnutrition - and dysphagia management of the Stuurgroep Ondervoeding, the ESPEN and of the Dutch Association for Throat, Nose and Osteopathy (NVKNO) have been taken into account. The extra burden of this study to the participants is limited and neither are there extra risks expected.

It is not possible to conduct this study with competent subjects only since this group is not representative of the current nursing home population. Participants will not be exposed to risk proceedings. Blood is taken, though this is done by knowledgeable and experienced staff. The amount of blood that is collected does not cause problems in this population.

Contacts

Public
Universiteit Maastricht

Universiteitssingel 50
Maastricht 6202 AZ
NL
Scientific
Universiteit Maastricht

Universiteitssingel 50
Maastricht 6202 AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. male or female nursing home resident * 65 years of age
2. diagnosis of (risk on) malnutrition based on the validated short nutritional assessment questionnaire for residential care (SNAQrc)
3. diagnosis of oropharyngeal dysphagia based on the 90 mL water swallow test (WST) according to Dutch guidelines and subsequent assessment by speech and language therapist (SLT)
4. admitted to * or living in a somatic - or psychogeriatric ward in one of the participating nursing homes
5. written informed consent (IC) from participant or legal representative

Exclusion criteria

- consequent daily use of protein- and/or energy containing ONS in the past 4 weeks
- consequent use of enteral - or parenteral nutrition at the moment of screening or 4 weeks prior to screening
- investigator*s uncertainty about the willingness or ability of the subject to comply with the protocol requirements
- known allergy or intolerance to any ingredient of the intervention product, e.g. lactose intolerance or galactosemia

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2019
Enrollment:	156
Type:	Actual

Ethics review

Approved WMO

Date:	04-07-2019
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL68301.068.18
Other	zal voordat eerste deelnemer wordt geincludeerd,geregistreerd worden bij trialregister.nl