A randomized, double-blind controlled trial on the effects of the mouthrinse containing edible mushroom (shiitake) extract on dental plaque acidogenicity and microbial composition

Published: 12-02-2009
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Main objective is to investigate if low molecular weight fraction of edible mushroom Shiitake extract possesses clinically relevant caries preventive properties

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

Summary

ID

NL-OMON33940

Source
ToetsingOnline

Brief title
NUTRIDENT

Condition

- Other condition

Synonym
caries, dental decay

Health condition

caries preventie

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit
Source(s) of monetary or material Support: EU

Intervention

Keyword: acidogenicity, dental plaque, functional foods, shiitake

Outcome measures

Primary outcome

Amount of organic acids in plaque and microbial composition of plaque before

and after each test period

Secondary outcome

Amount of dental plaque before and after each test period

Study description

Background summary

The proposed randomized controlled trial is a part of the Specific Targeted Research or Innovation Project (STRIP) granted by EU sixth framework program, under thematic priority *Food Quality and Safety*, entitled: "Towards functional foods for oral health care - isolation, identification and evaluation of beverage and food components with anti-caries and/or anti-gingivitis activities" (EU contract FOOD-CT-2006-36210, project acronym "NUTRIDENT*, start of the project 01-10-2006). In vitro results obtained within this project indicate that low molecular weight fraction of edible mushroom Shiitake extract may have an anti-gingivitis and caries-preventive potential. The outcome of the proposed clinical study is of major importance in further development of oral care product(s) that would have beneficial effects on oral health.

Study objective

Main objective is to investigate if low molecular weight fraction of edible

mushroom Shiitake extract possesses clinically relevant caries preventive properties

Study design

Double-blind, three-leg cross-over randomized controlled clinical trial

Intervention

All volunteers will rinse their mouth twice-daily in a randomised order with 1) a mouthwash containing low molecular weight fraction of edible mushroom Shiitake extract, 2) a placebo mouthwash or 3) a positive control Meridol® (GABA Int, Switzerland) mouthwash, for two weeks, with a 2-week washout period in between each rinsing period.

Study burden and risks

Burden: Study subjects will have to visit ACTA eight times for 20 min during a period of 13 weeks and will have to abstain from toothbrushing for 48 h and from any food and dring intake for 2 h before each visit.

Risks: There are no risks associated with participation to the study.

Benefit: Study participants are expected to benefit from professional oral hygiene procedure that will be carried out at the start of the study.

Group relatedness: Two-week long washout periods have been shown to be sufficiently long to eliminate carry-over effect of Meridol (Gerardu et al., 2006).

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

Healthy males and females that would:
* Be 18 years of age or older
* Be in good general health as determined by the investigator based on a review of the medical history/update
* Possess at least three posterior teeth (premolars/molars) in each quadrant (with no partial dentures, orthodontic banding or wires)

Exclusion criteria

* Have not passed all inclusion criteria
* Have used antibiotics less than three months prior the start of the study
* Have untreated caries or periodontal disease
* Have reduced stimulated salivary flow (< 0.7 ml/min)

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Double blinded (masking used)
Control:	Uncontrolled

Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-03-2009
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	12-02-2009
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL21480.029.08