A phase I/II, double blind, cross-over design, placebo controlled, pilot study to assess the effect and tolerability of multiple oral doses of phytosphingosine in Sjögren’s patients.

No registrations found.

Ethical review	Not applicable
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25165

Source
NTR

Brief title
Oral Hygiene Xerostomia

Health condition

Xerostomia, Sjogren disease, Candida albicans, phytosphingosine

Sponsors and support

Primary sponsor: Section Oral & Maxillofacial Surgery
University Medical Center Groningen
Hanzeplein 1
9713 GZ Groningen
Source(s) of monetary or material Support: ZON-MW
Laan van Nieuw Oost Indië 334
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The Netherlands
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Intervention

Outcome measures

Primary outcome

Reduction in C. albicans and or S. mutans relative to control.

Secondary outcome

Tolerability.

Study description

Background summary

N/A

Study objective

N/A

Study design

One hour treatment repeated crossed over after 14 days.

Intervention

Single treatment with pastilles containing phytosphingosine or placebo. Wash out period at least 14 days.

Contacts

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Eligibility criteria

Inclusion criteria

1. Primary Sjögren’s syndrome female adult patients, diagnosed following EU criteria [1];

2. Stimulated whole salivary flow rate >0.30 ml/min, stimulated parotid salivary >0.15 ml/min;

3. Saliva positive for S. mutants and C. albicans (all m.o. cfu≥103);

4. Not pregnant;

5. No use of xerogenic drugs or drugs that might affect oral ecology;

6. Willing and able to adhere to the study visit schedule and other protocol requirements;

7. Written informed consent signed.

Exclusion criteria

1. Use of antibiotic medication less than 3 weeks before screening;

2. Dentures;

3. Smoking;

4. Current or history of drug and/or alcohol abuse;

5. In parallel participation in another trial with an investigational product.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Non controlled trial

Control: Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2009
Enrollment:	20
Type:	Actual

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	NL1769
NTR-old	NTR1879
Other	UMCG : PHS-01
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A