

Probiotic *Streptococcus salivarius* to reduce symptoms of denture stomatitis and oral colonization caused by *Candida albicans*

Submission date 24/02/2020	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 27/02/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 27/02/2020	Condition category Oral Health	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Denture stomatitis (DS) is characterized by soreness, pain, discomfort, and denture mobilization, and is the cause of multiple visits to the dental office. DS may also increase the risk of pulmonary (lung) and other systemic infections, particularly in institutionalized elderly subjects. The aim of this study is to evaluate the effects of a probiotic preparation, containing *Streptococcus salivarius* strain BLIS®K12, in *Candida albicans* positive patients affected by DS, and the duration of these effects.

Who can participate?

Patients of both sexes and all ages with one or both completely edentulous arches, affected by denture stomatitis

What does the study involve?

All patients are instructed to perform scrupulous mechanic denture and oral hygiene daily, to refrain from 24 hours wearing of the denture, and invited not to use oral rinses containing antimicrobial substances. Patients randomly allocated to the experimental group (EXP) are then invited to perform mechanic denture and oral hygiene as previously explained, and to take for 30 days one tablet of Bactoblis® in the evening, just before going to sleep, allowing the tablet to dissolve in the mouth, and to refrain from drinking for the next 60 minutes. Patients randomly allocated to the control group are invited to perform mechanic denture and oral hygiene as previously explained for 30 days.

What are the possible benefits and risks of participating?

Possible benefits are healing from denture stomatitis and improved quality of life. Risks are that the denture stomatitis persists without differences with the control group. No risks have been reported concerning the administration of probiotic *Streptococcus salivarius*.

Where is the study run from?

Sapienza University of Rome (Italy)

When is the study starting and how long is it expected to run for?
January 2017 to December 2019

Who is funding the study?
Pharmextracta SpA (Italy)

Who is the main contact?
Dr Maurizio Speroni
m.speroni@pharmextracta.com

Contact information

Type(s)
Scientific

Contact name
Dr Dario Di Nardo

ORCID ID
<https://orcid.org/0000-0002-5054-0828>

Contact details
Department of Oral and Maxillo Facial Sciences, Sapienza University of Rome
Via Caserta, 6
Rome
Italy
00161
+39 (0)3393935527
dario.dinardo@uniroma1.it

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
4790

Study information

Scientific Title
Probiotic Streptococcus salivarius to reduce symptoms of denture stomatitis and oral colonization caused by Candida albicans

Study objectives

Probiotic *Streptococcus salivarius* can reduce denture stomatitis.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 22/11/2017, Ethical committee of the Sapienza University of Rome Viale del Policlinico (155 - 00161 Rome, Italy; +39 (0)649979822; comitato.etico@policlinicoumberto1.it), ref: 4790 Protocol n. 112/17

Study design

Single-centre interventional randomised study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Home

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Denture stomatitis caused by *Candida albicans*

Interventions

Fifty adult denture wearers affected by denture stomatitis were enrolled and randomly divided into two groups: the experimental group was instructed to perform careful oral and denture hygiene and to use the probiotic *Streptococcus salivarius* mouth rinse for 30 days (Bactoblis® (Pharmaextracta Spa, Pontenure, Piacenza, Italy), containing 10(9) cfu of the probiotic strain *Streptococcus salivarius* BLIS®K12); the control group received only conventional hygiene instructions to clean dentures. Patients were evaluated for signs of DS at the beginning, the end and 30 days after the treatment. Microbiological samples were obtained at the beginning of the study and at the end of treatment to enumerate *Candida albicans* cells.

Intervention Type

Supplement

Primary outcome measure

1. Presence/absence of subjective pain in the oral mucosae assessed by asking patients at 30 and 60 days
2. Presence/absence of sensation of dryness of the mouth assessed by asking patients at 30 and

60 days

3. Visual signs of denture stomatitis assessed by clinical observation made by clinician using Newton's classification at 30 and 60 days

Secondary outcome measures

1. Number of *Candida albicans* (cfu/ml) measured from a specimen obtained by streaking a cotton swab along the gingiva, at 0 and 30 days

2. Number of *Candida albicans* (cfu/ml) measured from a specimen of saliva at 0 and 30 days

Overall study start date

15/01/2017

Completion date

30/12/2019

Eligibility

Key inclusion criteria

1. At least one totally edentulous dental arch
2. A full arch well-fitting removable acrylic denture
3. Subjective discomfort/pain in relation to denture
4. Clinical signs of denture stomatitis

Participant type(s)

Patient

Age group

Senior

Sex

Both

Target number of participants

50

Key exclusion criteria

1. Use of adhesives for denture stabilization
2. Assumption of antibiotics in the last 30 days
3. Systemic diseases influencing homeostasis of the oral mucosae

Date of first enrolment

01/01/2019

Date of final enrolment

28/02/2019

Locations

Countries of recruitment

Italy

Study participating centre
Sapienza University of Rome
Department of oral and maxillofacial sciences
Via Caserta, 6
Rome
Italy
00161

Sponsor information

Organisation
Pharmextracta SpA

Sponsor details
Via G. Natta, 28
Pontenure (PC)
Italy
29010
+39 (0)523510848
m.speroni@pharmextracta.com

Sponsor type
Industry

Website
<http://www.pharmextracta.com>

Funder(s)

Funder type
Industry

Funder Name
Pharmextracta SpA

Results and Publications

Publication and dissemination plan
Publication as an original article In an open access international medical journal as soon as possible.

Intention to publish date

30/03/2020

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Claudio Passariello (claudio.passariello@uniroma1.it).

IPD sharing plan summary

Available on request