

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

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<b>Registration date</b> 27/02/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 27/02/2020	<b>Condition category</b> 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

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## Additional identifiers

**Protocol serial number**  
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

## **Study type(s)**

Treatment

## **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(s)**

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

## **Key secondary outcome(s)**

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

## **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

**Healthy volunteers allowed**

No

**Age group**

Senior

**Sex**

All

**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

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**Sponsor information****Organisation**

Pharmextracta SpA

## **Funder(s)**

### **Funder type**

Industry

### **Funder Name**

Pharmextracta SpA

## **Results and Publications**

### **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](mailto:claudio.passariello@uniroma1.it)).

### **IPD sharing plan summary**

Available on request