ISRCTN14751782 https://doi.org/10.1186/ISRCTN14751782

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

Registration date
27/02/2020

Overall study status
Completed

Last Edited
27/02/2020

Condition category
Oral Health

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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 Streptoccoccus 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

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

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 Policinico (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
Rome
Italy
00161

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).

IPD sharing plan summary
Available on request