Clinical Trial Details (PDF Generation Date :- Mon, 07 Aug 2023 05:07:48 GMT)

CTRI Number	CTRI/2022/09/045368 [Registered on: 09/09/2022] - **Trial Registered Prospectively**
Last Modified On	18/05/2023
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Probiotic
Study Design	Randomized, Parallel Group, Placebo Controlled Trial
Public Title of Study	Safety of Streptococcus Salivarius in Healthy Individuals
Scientific Title of Study	A Prospective, Block Randomized, Double-Blind Placebo-Controlled Study to Study the Safety Profile of Streptococcus Salivarius UBSS-01 in Healthy Individuals

Secondary IDs if Any

Secondary ID	Identifier
NIL	NIL

Details of Principal Investigator or overall Trial Coordinator (multi-center study)

Details of Principal Investigator	
Name	Dr Ravi K S
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Details Contact Person (Scientific Query)

Details Contact Person (Scientific Query)	
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Details Contact Person (Public Query)

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Source of Monetary or Material Support

Source of Monetary or Material Support
> Unique Biotech Limited, Plot No 2, Phase II, Alexandria Knowledge Park Kolthur Village, Shameerpet Mandal Ranga Reddy Dist, Hyderabad- 500078

Primary Sponsor

Primary Sponsor Details	
Name	Unique Biotech Limited
Address	Unique Biotech Limited, Plot No 2, Phase II, Alexandria Knowledge Park Kolthur Village, Shameerpet Mandal Ranga Reddy Dist, Hyderabad- 500078
Type of Sponsor	Pharmaceutical industry-Indian

Details of Secondary Sponsor

Name	Address
NIL	NIL

Countries of Recruitment

List of Countries
India

Sites of Study

Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
Dr Rajesh Venkataraman	Adichunchanagiri Hospital and Research Centre	Room No:09,Second Floor,Department of ENT Adichunchanagiri Hospital and Research Centre Mandya KARNATAKA	9980038331 rajeshvenky_research @hotmail.com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Institutional Ethics Committee of AH & RC, Adichunchanagiri Hospital & Research Centre	Approved	27/08/2022	No

Regulatory Clearance Status from DCGI

Status	Date
Not Applicable	No Date Specified

Health Condition / Problems Studied

Health Type	Condition
Healthy Human Volunteers	Healthy

Intervention / Comparator Agent

Type	Name	Details
Intervention	Streptococcus Salivarius UBSS-01	Each sachet contain of Streptococcus Salivarius UBSS-01 contains 10 billion colony-forming units-once a day at night for 30 days
Comparator Agent	Placebo	Each sachet contains only excipients-once a day at night for 30 days

Inclusion Criteria

Inclusion Criteria	
Age From	18.00 Year(s)
Age To	65.00 Year(s)
Gender	Both
Details	1.Healthy adults of aged 18-65 years 2.Body mass index of

	18.5-35 kg/m2 3.Normal or acceptable physical exam, vital signs and laboratory values 4.No known food allergies or intolerances

Exclusion Criteria

Exclusion Criteria	
Details	1.History of active or chronic dental or medical disease 2.Individuals who were prone to gas, bloating or diarrhoea 3.Pregnant or planning to become a pregnant, or breastfeeding 4.Received antibiotic treatment within last month or required to take antibiotics during study period 5.Those who have used probiotic supplements with in last month or consumed probiotic rich foods such as yogurt or kefir, used over-the-counter laxatives or any other medications, supplements, or products that could have influenced the endpoints in this study. 6.Those who are current users of tobacco products, vaping products, cannabis, and/or nicotine replacement therapy 7.Individuals who are frequent users of alcohols

Method of Generating Random Sequence	Other
Method of Concealment	Sequentially numbered, sealed, opaque envelopes
Blinding/Masking	Participant and Investigator Blinded

Primary Outcome

Outcome	Timepoints
Incidences of adverse events (AE) in the Streptococcus salivarius UBSS-01 and placebo group during the treatment.	Day 1 to Day 30

Secondary Outcome

Outcome	Timepoints
medication compliances of Streptococcus salivarius UBSS-01 as a probiotic candidate in healthy individuals.	Day 1 to Day 30

Target Sample Size	**Total Sample Size=**60 **Sample Size from India=**60 **Final Enrollment numbers achieved (Total)=**80 **Final Enrollment numbers achieved (India)=**80
Phase of Trial	Phase 3/ Phase 4
Date of First Enrollment (India)	12/09/2022
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**0 **Months=**1 **Days=**0
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Completed
Publication Details	Wescombe, P.A., Hale, J.D.F., Heng, N.C.K., Tagg, J.R., 2012. Developing oral probiotics from Streptococcus salivarius. Future Microbiol. 7, 1355–1371. https://doi.org/ 10.2217/fmb.12.113. Burton JP, Cowley S, Simon RR, McKinney J, Wescombe PA, Tagg JR. Evaluation of safety and human tolerance of the oral probiotic Streptococcus salivarius K12: a randomized,

placebo-controlled, double-blind study. Food and chemical toxicology. 2011 Sep 1;49(9):2356-64.

Brief Summary

A dysbiosis of microbiota can cause a variety of conditions depending on where it is found. With increased awareness of the importance of maintaining a healthy microbiota, probiotics have emerged as an impressive method for treating dysbiosis-related conditions. Streptococcus salivarius is a pioneer species that colonizes the human oral cavity from birth and continues to be a dominant member of the commensal oral microbiota throughout life. It is also found in human breast milk and has been found in a variety of non-pasteurized indigenous fermented milk products. The increased interest in S. salivarius' probiotic potential stems from its numerical dominance in the oropharynx, the production by some strains of a particularly diverse array of anti-competitor molecules [bacteriocins and bacteriocin-like inhibitory substances (BLIS)], and demonstrations of its beneficial application to the relief or control of various upper respiratory tract ailments such as strep sore throat, otitis media.
In this study we aim to the safety profile and medication compliances of Streptococcus salivarius UBSS-01 as a probiotic candidate in healthy individuals.