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Senses™ Oral Swabsticks clinical trial: improving dry mouth and other oral health parameters as compared to placebo and Oralieve Mouth Spray among 65–80-year-old care home residents

Submission date
16/05/2021

Recruitment status
No longer recruiting

Registration date
07/06/2021

Overall study status
Completed

Last Edited
24/01/2023

Condition category
Signs and Symptoms

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Dry mouth (xerostomia, or reduced salivary flow) is one of the most common oral health issues faced by elderly patients. The treatments that are currently used to help reduce the symptoms are not as good as we would like them to be. There is a new herbal formula that may work better. The reason we are doing this research is to find out if the new treatment which contains Spilanthes (or Spilanthol which is an extract of Spilanthes) is better than Oralieve Moisturising Mouth Spray which is currently being used.

Who can participate?
We are inviting all adults above the age of 65 years with xerostomia who reside at one of the Quantum Care homes involved to participate in the research on Senses Oral Swabstick for xerostomia.

What will the study involve?
Because we want to be sure that Senses Oral Swabstick is better than the currently available drugs for treating dry mouth, we need to compare them. To do this, we will put people taking part in this research into three groups. The groups are selected at random.

Participants in one group will be given the Senses Oral Swabstick A (containing Spilanthes extract) while participants in another two groups will be given the Placebo Oral Swabstick B (without Spilanthes extract) and Oralieve Moisturising Mouth Spray, an artificial Saliva Oral Spray (this is currently being used for Dry mouth) respectively.

This will be given to participants 3 times a day for 14 days by their care giver who will be trained in the application procedure. There will be a washout period of 7 days where no treatment will be given to them during this period.
At the end of 21 days, they will be put on the next treatment (Oral Swabstick A/B or Oral Spray). This change to the next group is to decrease between-treatment interindividual variability.

Similarly, at the end of the next 14 days, there will again be a washout period of 7 days where no treatment will be given.
At the end of 21 days, they will be put on the next treatment (Oral Swabstick A/B or Oral Spray for 14 days. Oral examination using photographs and videos along with patient perception about changes in dry mouth and overall mouthfeel using a questionnaire will be recorded at baseline or 0 and after 7 and 14 days of every treatment.
They will receive the treatment of their dry mouth condition according to national guidelines.

What are the possible benefits and risks of participating?
There may not be any direct benefit for participants but the trial is likely to help us find the answer to the research question. There may not be any benefit to society at this stage of the research, but future generations are likely to benefit.
This drug does not have any side effects or risks. However, we will follow participants closely and keep track of any unwanted effects or any problems.
The swabsticks are pH neutral, have a pleasant apple flavour, especially developed for those with taste sensitivities and the main ingredient, Spilanthol, is known to improve salivary flow and overall mouthfeel. We know of no problem or risks associated with it.

Where is the study run from?
Quantum Care is a charity with 26 care homes in the home counties. Their head office in Welwyn Garden City (UK) is running the trial.

When is the study starting and how long is it expected to run for?
May 2020 to May 2024

Who is funding the trial?
Loba Ltd (UK)

Who is the main contact?
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Contact information

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Additional identifiers

Integrated Research Application System (IRAS)
299811

Study information

Scientific Title
Efficacy of Senses™ Oral Swabstick in improving dry mouth and other oral health parameters as compared to placebo and Oralieve Mouth Spray among 65–80-year-old residents of Quantum Carehome - a randomised controlled double blinded cross over clinical trial

Acronym
SOSCT

Study objectives
Senses™ Oral Swabstick improves dry mouth and other oral health parameters as compared to placebo and Oralieve Mouth Spray.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Randomized multi-centre controlled double blinded cross over clinical trial

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Dry mouth (xerostomia) and related oral health parameters

Interventions

The substance that we are testing in this research is called Spilanthol (Spilanthes Extract- Also commonly known as Toothache plant). We want to test the Swabsticks containing Spilanthol on people who have xerostomia/dry mouth. Forty-five adults above the age of 65 with xerostomia who reside at Quantum Care homes will be recruited for this study using randomization.

Senses Oral swabsticks containing Spilanthes will be applied onto the inner aspects of the cheeks three times daily for two weeks. After a gap period of one week (washout period), this will be repeated twice in the same way with Oral swabsticks without Spilanthes extract (placebo) and then with Oralieve Mouth Spray containing commonly used medications for xerostomia.

Remote Oral examination using photographs and videos along with patient perception about changes in dry mouth and overall mouthfeel using a questionnaire will be recorded at baseline or 0 and after 7 and 14 days of every treatment. We will follow up the patients closely and keep track of any unwanted effects or any problems. The information that we collect from this research project will be kept confidential.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Senses Oral swabsticks

Primary outcome(s)
Dry mouth Score using a 100 mm Visual Analogue Scale at baseline, 7 and 14 days

Key secondary outcome(s)
1. Clinical signs of dry mouth according to recommendations of Navazesh et al. (2003). Dryness and cracking of the corners and/or the vermilion borders of the lips were scored as 0 (normal), 1 (dry vermilion border), 2 (dry, chapped and/or fissured tissue), or as 3 (angular chelitis, redness, or fissuring at the commissure) using remote diagnosis through clinical pictures and videos at baseline, 7 days and 14 days of each treatment arm
2. Plaque index and Gingival index to assess overall oral health using remote diagnosis through clinical pictures and videos at baseline, 7 days and 14 days of each treatment arm
3. Salivary pool, scored as 0 (absence of it or any of the above-mentioned symptoms), or 1 (symptoms present) at baseline, 7 days and 14 days of each treatment arm
4. Self-assessment of halitosis (hand over mouth technique) on a 5- point Likert scale at baseline, 7 days and 14 days of each treatment arm
5. Patients' perception of overall mouthfeel using Bluestone Mouthfeel Questionnaire at baseline, 7 days and 14 days of each treatment arm
6. Xerostomia Quality of Life questionnaire
7. Tolerance using using a 100 mm Visual Analogue Scale at baseline, 7 days and 14 days of each treatment arm
8. Adverse effects, if any present -at baseline, 7 days and 14 days of each treatment arm

Completion date
11/05/2024

Eligibility

Key inclusion criteria
1. Residents of Quantum Care homes
2. Between 65 to 80 years of age
3. Belonging to both the gender
4. Have complained of dry mouth in the past one month
5. No simultaneous participation in another studies.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Lower age limit
65 Years

Upper age limit
80 Years

Sex
All

Total final enrolment
45

Key exclusion criteria
1. Participants with known hypersensitivity to ingredients in the product
2. Participant’s taking medications to increase salivary secretion in the past six months
3. Participant’s with comorbid disease of salivary gland; Participant’s with any viral/bacterial /fungal infections
4. Participants under radiotherapy

Date of first enrolment
01/11/2023

Date of final enrolment
01/02/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Quantum Care Ltd
4 Silver Court
Watchmead
Welwyn Garden City
United Kingdom
AL7 1TS

Sponsor information

Organisation
Quantum Care

Funder(s)

Funder type
Industry

Funder Name
Lobal Ltd

Results and Publications

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other