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The safety and efficacy of an herbal chlorhexidine gel on bad breath caused by oral bacteria

Submission date 26/07/2017	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 24/10/2017	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 11/01/2018	**Condition category** Oral Health	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
Halitosis (malodor, “bad breath”) is a common, yet socially stigmatizing condition that affects roughly 30-50% of the population. Ninety percent of all cases of halitosis are estimated to come from the oral cavity, and the remainder from the gut microbiome and systemic disease. Halitosis that originates in the oral cavity is caused by volatile sulfur compounds (VSC) such as hydrogen sulfide (H2S) and Methanethiol (CH3SH, “MeSH”), which are byproducts of the sulfur-metabolizing bacteria that reside primarily in periodontal pockets, cheek mucosa and the dorsum (back) of the tongue. The substrates (the surface or material that bacteria grows on) of these bacteria are the sulfur-containing amino acids (e.g. cysteine, methionine) which are commonly found in everyday food sources. Thus, halitosis of oral origin is circadian, rising and falling in combination with ingestion and varying in intensity throughout a 24-hour period. Therefore, the aim of this study is to test the efficacy of an Herbal Chlorhexidine oral gel (HCG) in subjects with chronic oral halitosis to determine the reduction in oral bacteria and associated VSC.

Who can participate?
Adults aged 18 to 70 who have halitosis.

What does the study involve?
Prior to the beginning of the study, participants have tongue scrapings sampled and measured for bacteria and provide breath samples that are measured for odor (volatile sulfur compounds). They are also administered a quality of life questionnaire. Participants are randomly allocated to one of two groups. Those in the first group receive an oral gel containing study constituents (treatment). Those in the second group receive an oral gel without study constituents (placebo or dummy). Both groups are instructed as to how and when to apply the gel to the tongue. Following a one-week application period, all parameters are measured again (e.g. tongue bacteria, breath odor, and questionnaire). Following a one-week period, all participant s parameters are taken again and the measurements compared between treatments.

What are the possible benefits and risks of participating?
Participants may benefit from using the gel as it contains botanical ingredients known for their impact on halitosis so it is anticipated the treatment gel will have a longer lasting and more substantial affect. The treatment gel contains material commonly available in many mouthwashes with side-effects including dry mouth and unpleasant taste.

Where is the study run from?
Periodontal Solutions (USA)

When is the study starting and how long is it expected to run for?
May 2018 to April 2018

Who is funding the study?
Investigator initiated and funded (USA)

Who is the main contact?
Mr Paul Bobrowski
Dr Stephanie Gonzalez

Contact information

Type(s)
Public

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Type(s)
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
17-33143

Study information

Scientific Title
A double-blind placebo controlled study to determine the effectiveness of a new oral gel for halitosis

Study objectives
Intervention with an herbal-chlorhexidine gel applied to the dorsum of the tongue reduces volatile sulfur compounds (VSC) and oral malodor better than tongue brushing alone.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Single-center randomised double-blind placebo-controlled interventional investigation

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Halitosis (malodor)

Interventions
Current interventions as of 11/01/2018:
Participants are recruited from a pool of current patients as well as new. Baseline data is

recorded. This includes: organoleptic measurements, volatile sulfur compound (VSC) [H2S, MeSH] levels, tongue scraping (microbiota) and self-assessment survey.

Participants are randomly allocated to receive either treatment or placebo (unmarked, coded) for a 7-day period and assessments compared to baseline. The treatment consists of a Herbal-Chlorhexidine gel with tongue-scraping. The placebo consists of a flavored gel with tongue-scraping.

Analysis includes changes in microbiota, organoleptic indices, volatile sulfur compound (VSC) levels, and quality of life (QOL) ratings.

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Analysis includes changes in microbiota, organoleptic indices, volatile sulfur compound (VSC) levels, and quality of life (QOL) ratings. Each analysis is repeated after each intervention period.

Intervention Type
Other

Primary outcome measure
Current outcome measures as of 11/01/2018:
1. Microbiota is measured by standard AOAC methodology (e.g. plate count) via a registered independent laboratory from tongue scrapings at the beginning and end of the trial period (Days 1 and 7).
2. VSC (GC) is measured using a halimeter (e.g. OralChroma) at the beginning and end of the trial period (Days 1 and 7).
3. Organoleptic is measured using the gastight syringe method of Kim et al (2009) at the beginning and end of the trial period (Days 1 and 7).

Previous outcome measures:
1. Microbiota is measured by standard AOAC methodology (e.g. plate count) via a registered independent laboratory from tongue scrapings at days one, eight, 15 and 22
2. VSC (GC) is measured using a halimeter (e.g. OralChroma) at days one, eight, 15 and 22
3. Organoleptic is measured using the gastight syringe method of Kim et al (2009) at days one, eight, 15 and 22

Secondary outcome measures
Current secondary outcome measures as of 11/01/2018:
Quality of life is assessed using a modified Halitosis Associated Life Quality Test (HALT) at the beginning and end of the trial period (Days 1 and 7).

Previous secondary outcome measures:
Quality of life is assessed using a modified Halitosis Associated Life Quality Test (HALT) questionnaire at days one, eight, 15 and 22.

Overall study start date
30/05/2017

Completion date
31/05/2018

Eligibility

Key inclusion criteria
1. Informed consent
2. Availability at the investigational site at the specified study intervals and sampling times
3. Baseline organoleptic malodor score of >2
4. Baseline total VSC > the threshold level of GC (OralChroma®, Breathtron®, Halimeter®)
5. > 20 remaining permanent teeth (tooth brushing > qd)
6. Good oral hygiene/dental health
7. Ability to safely fast prior to at the specified study intervals and sampling times
8. Male and Females 18-70

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
70 Years

Sex
Both

Target number of participants
30

Key exclusion criteria
1. History of infectious disease
2. Current use of antibiotics, antimicrobials or during the trial period
3. Severe periodontal disease or extensive caries
4. Periodontal pocket > 6 mm in depth
5. Consumption of pre-, pro-biotics or other target gut microbiome supplements
6. Smoker
7. Allergies to any of the treatment constituents

Date of first enrolment
01/03/2018

Date of final enrolment
28/04/2018

Locations

Countries of recruitment
United States of America

Study participating centre
Periodontal Solutions
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Sponsor information

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Industry

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Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Anticipated publication date in high-impact peer-reviewed open access journal.

Intention to publish date
01/06/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analyzed during the current study will be available upon request from Paul Bobrowski email: paul@rainforest-inc.com and limited to current researchers in the field and redacted.

IPD sharing plan summary
Available on request