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Use of PerioTabsTM for patients with gingivitis

Submission date
23/10/2020

Recruitment status
No longer recruiting

Registration date
01/12/2020

Overall study status
Completed

Last Edited
05/10/2022

Condition category
Oral Health

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

Plain English summary of protocol

Background and study aims
Bacteria and microbial biofilm (plaque) are the most important causes of gum disease. Plaque control and efficient plaque removal are the two keystones for maintaining good oral health. Daily plaque accumulation can be prevented by tooth brushing and flossing, while plaque and calculus (hardened plaque) removal is performed during professional oral hygiene. However, efficient plaque control is not easy to obtain. Different toothpastes, gels and mouthwashes have been developed in an attempt to reduce bacterial adhesion to the teeth. Currently the gold standard is chlorhexidine (CHX), most widely recommended as a mouthwash, especially as a home-care treatment. Despite its proven antibacterial activity, CHX has been associated with staining and increased calculus formation. PerioTabsTM are a NitrAdineTM-based teeth and gum brushing solution. Several studies have demonstrated the anti-biofilm activity of NitrAdine in patients wearing removable dentures and orthodontic appliances. The aims of this study are to evaluate the effectiveness of 10-day use of PerioTabsTM combined with regular toothbrushing in patients suffering from gingivitis (gum inflammation), and secondly to investigate the presence of calculus, tooth discolouration and other adverse reactions.

Who can participate?
Adult patients with gingivitis

What does the study involve?
Patients are instructed to uses PerioTabsTM for 2 to 3 minutes once a day for 10 days in the evening. Each patient receives one PerioTabsTM box containing 10 small effervescent tablets and a container. Every evening, a fresh brushing solution is prepared by dissolving one small tablet in 15 ml of warm water using the provided container; while the tablet is dissolving, the toothbrush is immersed in the solution and left for 15 minutes, the time required for the tablet to completely dissolve. Patients then brush their teeth and gums (inner and outer) with the solution. It is recommended to immerse the toothbrush 2-3 times in the solution for a few seconds and brush again. After 2 minutes of brushing, patients are asked to rinse thoroughly their mouth with water and discard the remaining solution. No toothpaste or mouth rinse solution is used after the PerioTabsTM brushing session. The next morning, patients perform their routine daily oral hygiene using regular toothpaste. This scheme is maintained for the 10-day course of the treatment. Participants will be asked to attend professional oral hygiene before they begin the study and at follow-up visits at 10 days and 36 weeks after the beginning of the study. Participants will be asked to record the treatment’s unexpected effects in a diary.

What are the possible benefits and risks of participating?
Patients will be given a PerioTabsTM box and 10 capsules and will receive instructions for use. Patients will be able to contact their doctor for any eventuality. Patients will be regularly followed up to 6 months after the end of therapy.

Where is the study run from?
SICOR private dental office (Italy)

When is the study starting and how long is it expected to run for?
December 2017 to May 2019

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Prof. Paolo Giacomo Arduino
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Evaluating the clinical efficiency of PerioTabsTM, a new home-care based oral hygiene approach, for patients suffering from gingivitis: a prospective open-label single-arm pilot study

Acronym
PTBGNV

Study objectives
The use of PerioTabsTM, combined with regular tooth brushing for 10 days, could be useful in reducing plaque index and gingival index in patients suffering from gingivitis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 01/09/2019, CIR-Dental School (Turin, Via Nizza 230, Italy; +39 (0)11 6331522; email: not provided), ref: CIR-PO-pga2019/09

Study design
Prospective open-label single-arm pilot study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Gingivitis

Interventions
This is a prospective, open-label study, that involves giving a specific preparation (a non-antibiotic biofilm removal formulation based on NitrAdineTM) to a cohort of subjects with diagnosed gingivitis. Caucasian patients, attending a private practice office, Turin, Italy, are selected for the present study.

Patients are instructed to uses PerioTabsTM for 2 to 3 minutes once a day for 10 days in the evening. Each participating patient receives one PerioTabsTM box containing 10 small

effervescent tablets and a container. Every evening, a fresh brushing solution is prepared by dissolving one small tablet in 15 ml of warm water using the provided container; while the tablet is dissolving, the toothbrush is immersed in the solution and left for 15 minutes, the time required for the tablet to completely dissolve. Patients then brush their teeth and gums (inner and outer) with the solution. It is recommended to immerse the toothbrush 2-3 times in the solution for a few seconds and brush again. After 2 minutes of brushing, patients are asked to rinse thoroughly their mouth with water and discard the remaining solution. No toothpaste or mouth rinse solution is used after the PerioTabsTM brushing session. The next morning, patients perform their routine daily oral hygiene using regular toothpaste. This scheme is maintained for the 10-day course of the treatment.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
PerioTabsTM

Primary outcome measure
1. Gingival inflammation measured using Gingival Index (bleeding on probing) at baseline at 10 days and 36 weeks
2. Plaque formation measured using Plaque Index (PI) at baseline at 10 days and 36 weeks

Secondary outcome measures
1. Reported adverse events due to the treatment assessed from patient notes at the end of the study
2. Unexpected effects assessed from patient diary records collected at the end of the study

Overall study start date
01/12/2017

Completion date
01/05/2019

Eligibility

Key inclusion criteria
1. Aged ≥ 18
2. Gingivitis diagnosis
3. No detectable oral mucosal lesions
4. Able to complete the present clinical trial

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
30

Total final enrolment
30

Key exclusion criteria
1. Unable or unwilling to provide informed consent
2. Significant psychiatric or cognitive impairment
3. Pregnant or breast-feeding women
4. Subjects with an history of allergy for ingredients present in PerioTabsTM
5. Subjects with carious teeth
6. Subjects affected by periodontitis or suffering from oral acute conditions requiring antibiotics

Date of first enrolment
01/06/2018

Date of final enrolment
01/11/2018

Locations

Countries of recruitment
Italy

Study participating centre
SICOR dental private practice
Corso Sicilia 51
Turin
Italy
10133

Sponsor information

Organisation
University of Turin

Sponsor details

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Sponsor type
University/education

Website
https://www.dentalschool.unito.it/it

ROR
https://ror.org/048tbm396

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
The results of the primary and secondary endpoints along with any other reportable data will be published in a peer-reviewed journal.

Intention to publish date
01/01/2021

Individual participant data (IPD) sharing plan
The datasets generated and/or analyzed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/07/2022	05/10/2022	Yes	No