

Use of PerioTabs™ for patients with gingivitis

Submission date 23/10/2020	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 01/12/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 05/10/2022	Condition category Oral Health	<input type="checkbox"/> 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. PerioTabs™ are a NitrAdine™-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 PerioTabs™ 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 use PerioTabs™ for 2 to 3 minutes once a day for 10 days in the evening. Each patient receives one PerioTabs™ 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 PerioTabs™ 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 PerioTabs™ 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

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

Nil known

Study information

Scientific Title

Evaluating the clinical efficiency of PerioTabs™, 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 PerioTabs™, 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

Study type(s)

Treatment

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 NitrAdine™) 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 use PerioTabs™ for 2 to 3 minutes once a day for 10 days in the evening. Each participating patient receives one PerioTabs™ 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 PerioTabs™ 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)

PerioTabs™

Primary outcome(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

ROR

<https://ror.org/048tbm396>

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

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