Open, non-comparative, clinical investigation to evaluate the performance and safety of the medical device H42 (collagen paste for filling) in repairing periodontal pockets due to periodontitis.protocol V.1

franco.barattini[1,2]

[1]Opera CRO a Tigermed Company;
[2]10th Cozia Street, 300209, Timisoara, Romania (Europe)

federica.sbrocca

VERSION 1

APR 04, 2023

OPEN ACCESS

DOI:
dx.doi.org/10.17504/protocols.io.4r3l27rzxg1y/v1

Protocol Citation: franco.barattini 2023. Open, non-comparative, clinical investigation to evaluate the performance and safety of the medical device H42 (collagen paste for filling) in repairing periodontal pockets due to periodontitis.protocol. **protocols.io** https://dx.doi.org/10.17504/protocols.io.4r3l27rzxg1y/v1

Protocol status: In development
We are still developing and optimizing this protocol

Created: Apr 03, 2023

Last Modified: Apr 04, 2023

ABSTRACT

Research protocol to evaluate safety and overall performance of a collagen paste for filling (H42) in improving the healing of the gingiva by the reduction of Periodontal Pocket Depth (PPD) from 5 to 8 mm depth during the course of the study.

1 Open, non-comparative, clinical investigation to evaluate the performance and safety of the medical device H42 (collagen paste for filling) in repairing periodontal pockets due to periodontitis.

Investigators Sites

2 Two (2) sites in East Europe.

Duration for each patient

3 Twelve (12) weeks.

Timelines

4 Time 0
45 days: submission
160 days: Ethics Committees and Competent Authority approval
175 day: First Patient In
300 days: Last Patient In
390 days: Last Patient Out

Tested Product

5 H42 a collagen paste for filling manufactured by Bioteck.

Study objectives

6 Primary objectives

1. To evaluate the overall performance of H42 in improving the healing of the gingiva by the reduction of Periodontal Pocket Depth (PPD) from 5 to 8 mm depth at the final visit.
2. To evaluate the safety of the device through AE, SAE, ADE, SADE, DD incidence assessed by investigators at all visits and reported according to current legislation.

Secondary objectives

1. To evaluate during the study the performance of the tested device on the reduction of the following clinical indexes typically present in the periodontal disease:
- Clinical Attachment Level (CAL)
- Sulcus Bleeding Index (SBI)
- Bleeding On Probing (BOP)
- Plaque Index (PLI)
- Periodontal Pocket Depth (PPD)
2. To evaluate the improvement in general appearance of the gums at each timepoint.
3. To evaluate the inflammation of gingiva at each timepoint.
4. Evaluation of pain and absence of infection at w4, 8, and 12.
5. To assess the patient satisfaction.
6. To evaluate the global performance of the tested device assessed by Investigator.
7. To evaluate the global safety of the tested device assessed by Investigator and by the patient.

Study outcomes

7 Primary outcome

- PPD is defined as the distance from the gingival margin to the base of the gingival crevice and it will be measured at six sites per tooth (DV, V, MV, DL, L, ML), using a Williams periodontal probe. Only the pockets from 5 to 8 mm depth will be taken into account. PPD will be evaluated at week 4, 8, and 12 in comparison with baseline value (visit 1).
- Collection of AE, SAE, ADE, SADE, DD.

Secondary outcomes

- CAL, defined as the distance from the Cemento-Enamel Junction (CEJ) to the base of the probable crevice/pocket, and evaluated at week 4, 8 and 12 in comparison with baseline value (visit 1).
- SBI measured from four gingival units (mesial and distal papillary units and labial and lingual marginal units), using a periodontal probe with a 0.5 mm diameter tip. The scoring range around eight anterior teeth (four maxillary and four mandibular) is from 0 (healthy appearance and no bleeding on probing) to 5 (spontaneous bleeding with a marked swelling, and a change in colour). SBI will be evaluated at week 4, 8 and 12 in comparison with baseline value (visit 1).
- BOP, defined as presence/absence of bleeding within 15 seconds following pocket probing, is measured at week 4, 8 and 12 in comparison with baseline value (visit 1).
- PLI is measured for each tooth using the four-point scale Silness and Löe Plaque Index and will be evaluated at week 4, 8 and 12 in comparison with baseline value (visit 1).
- The Global Aesthetic Improvement Scale (GAIS) score assessed by the Investigator at week 4, 8,

and 12 in comparison with Visit 1 (day 0).
- The degree of satisfaction with the treatment on a four-point scale (very satisfied, satisfied, moderate satisfied or not satisfied) assess the patient at week 4, 8, and 12 in comparison with Visit 1 (day 0).
- The degree of inflammation of the gingiva, the pain and the absence of infection evaluated by Investigator using VAS (0-10).
- The global performance of the tested device assessed by Investigator (IGAP) through photos taken at each visit, at weeks 4, 8 and 12, compared to Visit 1 (day 0).
- The global safety of the tested device assessed by Investigator (IGAS) and by the patient (PGAS) at weeks 12.

Population for the study

8 Screened subjects: 38 (34 enrolled + 4 potential screening failures)
Enrolled subjects: 34 (30 evaluable subjects and 4 potential drop-outs.
Evaluable subjects: 30.
Each subject can have from 1 to 5 defects.

Population & treatments

9 Men or or women affected by periodontal pockets due to periodontitis.
All patients will be treated with the tested Medical Device.

Brief description

10 The enrolled patients will be visited at:
- Visit 1 day 0: Screening and Baseline
- Visit 2 week 1 (± 1 day): interim visit (only clinical evaluation, without probe)
- Visit 3 week 2 (± 2 days): interim visit (only clinical evaluation, without probe)
- Visit 4 week 3 (± 2 days): interim visit (only clinical evaluation, without probe)
- Visit 5 week 4 (± 4 days): interim visit
- Visit 3 week 8 (± 4 days): interim visit
- Visit 7 week 12 (± 4 days): End of the study visit

Treatments: as reported in the IFU, the administration will be performed at:
Day 0: first injection; multiple injection sites (one injection for each defect, with 5 defects maximum for each subject can be envisaged at Day 0 visit).
All the 34 enrolled subjects will follow the following procedure: following mechanical instrumentation of the piece to be treated (removal of plaque and root planning) and, after the administration of a bactericide product (chlorhexidine), the Investigator will keep the site dry and fill the pocket by injecting the tested device starting from the pocket floor. The site must be dry for

5 minutes after application.
Subjects will be instructed not to adopt a brushing technique that could damage the marginal tissues of the gums and not to use a toothbrush with hard bristles or an abrasive toothpaste.

Inclusion Criteria

11 - Men or women with age ≥ 25 and ≤ 65 years.
- Stage 3 generalized periodontitis.
- Subjects affected by periodontal pockets with probing depth (PD) in the range between 5 to 8 mm.
- Each subject can have from 1 to 5 defects.
- Subjects who follow in the previous two weeks instructions to oral hygiene (proper brushing techniques twice a day, proper flossing technique daily, and prevention: sugar intake, alcohol consumption, fluoride level.
- Subjects who agree to discontinue all dental procedures during the study.
- Subjects willing to provide signed informed consent to clinical investigation participation.
- Able to communicate adequately with the Investigator and to comply with the requirements for the entire study.

Exclusion criteria

12 - Use of aspirin and antiplatelet agents a week prior to treatment.
- Subjects affected by periodontal pockets.
- Subjects with history of allergy or hypersensitivity to the tested device or to its ingredients or hypersensitivity skin reaction to the investigational device based on intradermal test results at V1.
- Subjects presenting current o previous bleeding disorders.
- Subjects taking or having indications for anticoagulant therapy.
- Use of concomitant treatments or procedures aimed to improve gums health over the last six months before the clinical investigation enrolment, such as HA gel treatments, injection of fillers, surgery.
- Subjects suffering from infectious diseases including herpes simplex virus infection, active hepatitis or human immunodeficiency virus.
- Subjects at risk in term of precautions, warnings and contra-indications referred in the package insert of the clinical investigation device.
- Subjects with any dental aesthetic surgery in the preceding 12 months before the clinical investigation enrolment.
- Subjects with any active irritation or inflammation in the target areas of injection.
- Smoker subjects (≥10 cigarettes/day).
- Subjects unlikely to cooperate in the clinical investigation or with the clinical investigation visits.
- Pregnant woman, lactating woman, and man or woman of childbearing potential who is planning a pregnancy or is unwilling to use appropriate methods of contraception* during the study.
*Methods of contraception: hormonal contraceptive, intrauterine device or intrauterine system, double barrier method (condom with spermicide/diaphragm or cervical cap with spermicide), surgical sterilization (vasectomy, tubal ligation, etc.)

- Subjects with illness, or other medical condition that, in the opinion of the investigator, would compromise participation or be likely to lead to hospitalization during the study (e.g., epilepsy.
- Participation in an interventional clinical study or administration of any investigational agents in the previous 30 days.