

Can the results of non-surgical therapy of periodontitis be improved by the use of enamel matrix proteins?

Submission date 24/07/2020	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 29/07/2020	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 29/07/2020	Condition category Oral Health	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol

Background and study aims

Periodontal therapy is the treatment and prevention of gum disease. It aims to eliminate inflammation of the tissues around the affected teeth by removing bacteria from periodontal pockets below the gum line. The result is measured by the reduction of pocket depth. The non-surgical first phase of therapy may not be enough for advanced pockets and an extra surgical phase may be necessary. This study explores the possibility of improving the treatment outcomes of the non-surgical treatment phase by adding a medical device (enamel matrix derivative) to non-surgical retreatment of persisting deep pockets, thus avoiding the need for additional surgery.

Who can participate?

Adult patients with periodontitis

What does the study involve?

Two of the participant's teeth are randomly allocated to receive non-surgical retreatment either with or without use of the enamel matrix derivative (EMD). Repeated examinations are carried out over 12 months.

What are the possible benefits and risks of participating?

The possible benefits include avoidance of the need for periodontal surgery and improved diagnosis for affected teeth. There are no particular risks.

Where is the study run from?

University of Bonn (Germany)

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

July 2015 to July 2019

Who is funding the study?

Investigator initiated and funded with some support from Straumann Insitute (Switzerland)

Who is the main contact?
Prof. Søren Jepsen
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Contact information

Type(s)
Scientific

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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
Flapless application of enamel matrix derivative in periodontal retreatment: a multicenter feasibility randomized controlled trial

Study objectives
The adjunctive flapless application of EMD can lead to superior clinical outcomes compared to re-instrumentation of residual periodontal pockets alone.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 07/08/2020, Ethics Committee of the University Hospital Bonn, Biomedizinisches Zentrum, Sigmund-Freund-Str. 25, 53105 Bonn, Germany; +49 (0)228 287 51931; ethik@uni-bonn.de), ref: 049/15-ff

Study design

Multicenter randomized feasibility trial with split-mouth design

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Generalised periodontitis

Interventions

Adult patients presenting at re-evaluation after initial non-surgical periodontal therapy for generalised periodontitis with at least 2 teeth with residual probing pocket depths (PPD) ≥ 5 and ≤ 8 mm, with bleeding on probing (BOP). Two teeth in contralateral quadrants are randomised by coin toss to receive re-instrumentation either with (test) or without (control) adjunctive flapless administration of enamel matrix derivative (EMD). The follow-up is 12 months.

Intervention Type

Device

Phase

Not Applicable

Primary outcome(s)

Probing pocket depth measured in mm using a periodontal probe at baseline, 6 months and 12 months

Key secondary outcome(s)

Bleeding on probing (yes or no) measured using a periodontal probe at baseline, 6 months and 12 months

Completion date

01/07/2019

Eligibility

Key inclusion criteria

1. Adult patients
2. Two residual pockets with probing depth ≥ 5 mm and ≤ 8 mm, bleeding and probing (BOP), mobility $\leq$ degree 1 and without furcation involvement

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Total final enrolment

44

Key exclusion criteria

1. Full mouth plaque score (modified O'Leary et al. 1972) > 20%
2. Uncontrolled systemic disease, requiring high dose steroid therapy, radiation or other immune-suppressive therapy and history of malignant disease in the oral cavity or previous radiotherapy in the head or neck area
3. Pregnant or lactating females
4. Drug and alcohol abuse
5. Smoking > 10 cigarettes per day
6. inadequate restorative therapy or malocclusion

Date of first enrolment

01/10/2015

Date of final enrolment

01/07/2018

Locations**Countries of recruitment**

Germany

Italy

Study participating centre

University of Leipzig

Leipzig

Germany

04103

Study participating centre

Private practice

Torino

Italy

10143

Study participating centre
University of Rome, Sapienza
Rome
Italy
00185

Study participating centre
University of Bonn
Bonn
Germany
53111

Sponsor information

Organisation
University of Bonn

ROR
<https://ror.org/041nas322>

Funder(s)

Funder type
Industry

Funder Name
Investigator initiated and funded

Funder Name
Financial support from Institute Straumann AG (Switzerland)

Results and Publications

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes