ISRCTN14654696 https://doi.org/10.1186/ISRCTN14654696

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

Registration date
29/07/2020

Overall study status
Completed

Last Edited
29/07/2020

Condition category
Oral Health

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] 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
jepsen@uni-bonn.de

Contact information

Type(s)
Scientific

Contact name
Prof Søren Jepsen

ORCID ID
http://orcid.org/0000-0002-4160-5837

Contact details
Dept. of Periodontology, Operative and Preventive Dentistry
University of Bonn
Bonn
Germany
53111
+49 (0)228 287 22480
jepsen@uni-bonn.de

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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

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

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

Overall study start date
01/07/2015

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 ≤ degree 1 and without furcation involvement

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
40

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

Sponsor details
Welschnonnenstrasse 17
Bonn
Germany
53111
+49 (0)228 287 22480
jepsen@uni-bonn.de

Sponsor type
University/education

Website

http://www3.uni-bonn.de/the-university

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

Publication and dissemination plan
The researchers plan to submit a manuscript for publication in a high-impact peer-reviewed journal in the second half of 2020. No additional documents have been published.

Intention to publish date
31/12/2020

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