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Periodontal surgery and root surface decontamination by means of an erythritol based air-polishing

Submission date	Recruitment status	[_] Prospectively registered
29/10/2019	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
25/02/2020	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
28/03/2023	Oral Health	

Plain English summary of protocol

Background and study aims
The aim of this study is to evaluate the healing following surgical periodontal treatment with a special decontamination method that contains a powder made of a special type of sugar (Erythritol). This method is compared with the traditional cleaning method using hand instruments.

Who can participate?
Patients with a tooth with one root that is in need of further periodontal surgical therapy

What does the study involve?
During surgery, the gingiva will be raised and all inflammation tissue will be removed. Patients will be randomly allocated to one of two treatment procedures: a) test treatment consisting of careful removal of calculus (if present) with the tip of a blade and subsequent decontamination of the diseased root surface with erythritol using an air-polishing device and b) control group treatment consisting of thorough mechanical cleaning with hand curettes and ultrasonic instruments. Depth of periodontal pockets, the level of the measurable gingival attachment, the measurable bone level in the mouth and on the x-ray will be evaluated before the surgery and 12 months after.

What are the possible benefits and risks of participating?
With either study treatment (test or control) there will be a resolution of the inflammation in the treated area (tooth with a remaining deep clinical periodontal pocket which is at high risk for further bone loss) and thus arrest the progression of periodontitis and bone loss. The risks for participating are the general risks as for any type of dental periodontal surgery: bleeding, swelling, pain, which are actually in good control since the surgical protocol includes tight suturing of the operated area, and painkillers if need.

Where is the study run from?
University of Medicine and Pharmacy Cluj-Napoca (Romania)

When is the study starting and how long is it expected to run for?
September 2013 to July 2019

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
#201

Study information

Scientific Title
Healing following periodontal surgery and root surface decontamination by means of an erythritol based air-polishing

Acronym
CHIR_ERY

Study objectives

The clinical outcomes following conventional periodontal surgery (e.g. access flap using a simplified papilla preservation flap-SPPF) using the new erythritol powder applied with an air-polishing device are not inferior to those after the use of conventional hand and ultrasonic instruments in supra-alveolar bony defects.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 25/10/2013, Ethical Committee of the University of Medicine and Pharmacy Iuliu Hatieganu, Cluj-Napoca (Str. Emil Isaac nr 13, Cluj-Napoca, Romania; Tel: +40 (0)264 597256; Email: gluminita@umfcluj.ro), ref: #201/25.19.2013

Study design
Prospective randomized controled clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

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
Periodontitis with horizontal bone loss

Interventions
Thirty systemically healthy patients with periodontitis are included in the present study. Inclusion criteria are the presence of a single-rooted tooth with a probing pocket depth (PD) ≥ 6 mm associated with horizontal bone loss as detected at re-evaluation following nonsurgical periodontal therapy.

These sites are in need for further surgical therapy. Following flap preparation by means of simplified papilla preservation flap (SPPF) and removal of granulation tissue, patients are randomized (according to a computer-generated list, block randomisation procedure) as follows:
1. Test treatment consisting of careful removal of calculus (if calculus present) with the tip of a blade and subsequent air-polishing of the root surfaces with erythritol air-polishing (EMS, Switzerland)
2. Control group treatment consisting of thorough scaling and root planing (SRP) with hand curettes and ultrasonic instruments

Parameters PD, clinical attachment (CAL), bone sounding (BS), and radiological bone level (BL) are evaluated at baseline and 12 months postsurgically. The primary outcome variable is CAL-gain.

Intervention Type
Procedure/Surgery

Primary outcome measure
Clinical attachment (CAL), measured with a periodontal probe (PCP UNC 15, Hu Friedy) from the bottom of the periodontal pocket to the cementum-enamel-junction, at baseline and 12 months

Secondary outcome measures
Measured at baseline and 12 months:
1. Periodontal pockets measured with a periodontal probe (PCP UNC 15, Hu Friedy) from the bottom of the periodontal pocket to the gingival margin
2. Bone sounding (BS) measured with a periodontal probe (PCP UNC 15, Hu Friedy) under anaesthesia in contact to the bone within the periodontal pocket to the gingival margin
3. Radiological bone level (BL) measured on x-rays as the distance from the most apical point of the intrabony defect to the cemento-enamel junction

Overall study start date
15/09/2013

Completion date
16/07/2019

Eligibility

Key inclusion criteria
1. Patients have to present one single-rooted tooth with a PD ≥ 6mm and horizontal bone loss with a maximum 2 mm intrabony component as detected radiographically (experimental tooth)
2. Over 18 years old
3. Completed the nonsurgical periodontal therapy (initial anti-infective therapy) at least 3 months prior to study inclusion or be in the corrective phase of the periodontal treatment or engaged in SPT
4. Maintain a good level of oral hygiene [plaque control record (PCR) after O'Leary 1972 ≤ 25%] (O'Leary et al., 1972)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
30

Key exclusion criteria
1. Infectious/heart diseases that need prophylactic administration of antibiotics before dental treatments
2. History of diseases that may have influenced the severity/progression of periodontitis (e.g. Down Syndrome, HIV, Diabetes Mellitus type 1 and 2)
3. Liver diseases
4. Post-irradiation in the head/neck area
5. Periodontal surgery at the experimental teeth in the past 12 months
6. Clinical and/or radiographical signs of a vertical/horizontal tooth fracture or occlusal trauma at the test teeth
7. Pregnant or breastfeeding subjects
8. Patients smoking >10 cigarettes per day (Tonetti et al., 1995)

Date of first enrolment
04/11/2013

Date of final enrolment
14/12/2018

Locations

Countries of recruitment
Romania

Study participating centre
University of Medicine and Pharmacy Cluj-Napoca
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Sponsor information

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Sponsor type
University/education

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Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
A study protocol will not be available online. This will be provided only per request and a detailed description in the publication. Presentation at dental conferences and publication in specialized dental journals.

Intention to publish date
16/07/2020

Individual participant data (IPD) sharing plan
The dataset will not be available online according to the data protection law. The data will be held on university computers and accessed only by authorized study persons.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		24/08/2020	28/03/2023	Yes	No