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Possible benefits from nutritional supplements during periodontitis (gum disease) treatment

Submission date
10/08/2020

Recruitment status
No longer recruiting

Registration date
19/08/2020

Overall study status
Completed

Last Edited
28/02/2022

Condition category
Oral Health

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Periodontitis also called gum disease, is a serious gum infection that damages the soft tissue and, without treatment, can destroy the bone that supports the teeth. A healthy periodontium is the basis for oral health and for any further dental treatment. If there is an inflammation of the entire periodontium, it is called periodontitis. The inflammation continues from the gums into the depths and finally dissolves the bone around the roots. Periodontoal pockets form, i.e. the gums are no longer firmly attached to the root but a gap of several millimeters is formed between the gums and the gum tissue. In order to stop the inflammation and the decomposition of the tissue, these periodontal pockets are mechanically cleaned out under local anesthetic. In addition to mechanical cleaning, various measures are discussed to further improve the treatment results. Here, the intake of food supplements, which have a positive effect on wound healing and have an anti-inflammatory effect, could be beneficial. Such a dietary supplement is already commercially available (Nutrident Paro Pro ®) and would be compared with a placebo preparation in this study. A placebo preparation looks visually the same as the dietary supplement, but contains no active ingredients, only cellulose in this case.

Who can participate?
Adults over 18 years, with periodontitis stage III or IV.

What does the study involve?
The participants will be provided with the Nutrident Paro Pro® dietary supplement (Biogena) or an ineffective placebo (cellulose = non-resorbable and indigestible dietary fibre) (Biogena) for the duration of the study. The participants have to take the preparation twice daily for a period of two months. The data collected before and after taking the dietary supplement or placebo, both 8-12 weeks after the end of the last cleansing session and at the time of the 1-year "Recall with Status" session, will be analysed. The allocation of who receives a dietary supplement and who receives the placebo is randomized. Neither you nor the practitioner knows which product (dietary supplement or placebo) you are taking at home (this is not visible or traceable on the packaging, but is indicated by a code).

What are the possible benefits and risks of participating?
Benefits: The micronutrients contained in Nutrident Paro Pro® could lead to an improvement in

periodontal disease. In addition, an existing lack of micronutrients can be compensated. Taking the placebo preparation does not affect your health.
Risks: None

Where is the study run from?
Medical University of Vienna (Austria)

When is the study starting and how long is it expected to run for?
October 2019 to December 2021

Who is funding the study?
Medical University of Vienna (Austria)

Who is the main contact?
Prof. Hady Haririan, hady.haririan@med.sfu.ac.at

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
1324/2019

Study information

Scientific Title
The influence of the outcome of conservative periodontal therapy after intake of Nutrident Paro Pro during therapy - a placebo-controlled double-blind study

Study objectives
The concomitant use of Nutrident Paro Pro leads to significant clinical improvements during nonsurgical periodontal therapy compared to a placebo. The periodontal parameters "Bleeding on Probing" and "Probing Pocket Depths" improve significantly.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved (06/11/2019) Ethics committee of the Medical University of Vienna (Borschkegasse 8b /6
1090 Wien, Österreich; +43(0)1 404 00-21470; ethik-kom@meduniwien.ac.at), ref: 1324/2019

Study design
Randomized controlled double-blinded 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

Interventions
Patient recruitment: Patients with a periodontal screening index (CPITN >= 3) are referred to the Division of Conservative Dentistry and Periodontology, University Clinic of Dentistry, Medical University of Vienna. After the diagnosis of periodontitis stage III or IV, patients can give written consent to participate in the present study. Subsequently, they will be treated according to the Viennese Periodontal Concept. This comprises a full-mouth probing index (start of intake of verum or placebo), a supra- and subgingival cleaning of all affected tooth and root surfaces with ultrasonic devices and manual instruments under local anaesthesia. Patients take parallel to this non surgical periodontal treatment in a randomized way either a placebo or verum (Nutrident Paro Pro(R), Biogena) for 8-12 weeks. After the completion of non surgical periodontal therapy

and intake of the preparations after 8-12 weeks, a reassessment will take place (probing pocket depth, bleeding on probing). This will mark the end of the study. The lower bleeding on probing and probing pocket depths, the better is the outcome of periodontal therapy.

Randomization: The randomization will be performed by an independent dentist of the Division of Conservative Dentistry and Periodontology who is not involved in the study. The software Rand function, Excel 2016 for Mac, Microsoft, Redmond, VA, USA, will be used. The code to discriminate the verum from the placebo will be written on the bottom of the box by the company (Biogena) and only the above mentioned dentist will be informed about decoding.

Intervention Type
Supplement

Primary outcome measure
Probing pocket depth measured using a periodontal probe (PCP-12, Hu-Friedy) is inserted into the gingival sulcus at 6 sites per tooth at baseline and end of study (8 - 12 weeks)

Secondary outcome measures
Bleeding on probing measured using a periodontal probe (PCP-12, Hu-Friedy) is inserted into the gingival sulcus at 6 sites per tooth at baseline and end of study (8 - 12 weeks)

Overall study start date
01/10/2019

Completion date
01/12/2021

Eligibility

Key inclusion criteria
1. Aged ≥18 years
2. Periodontitis stage III or IV

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
42 participants

Key exclusion criteria
Pregnancy

Date of first enrolment
07/01/2020

Date of final enrolment
30/09/2021

Locations

Countries of recruitment
Austria

Study participating centre
Medical University of Vienna
University Clinic of Dentistry
Sensengasse 2a
Vienna
Austria
1090

Sponsor information

Organisation
Medical University of Vienna

Sponsor details
Spitalgasse 23
Vienna
Austria
1090
+43 1400704720
parodontologie-unizahnklinik@meduniwien.ac.at

Sponsor type
University/education

Website
http://www.meduniwien.ac.at

ROR
https://ror.org/05n3x4p02

Funder(s)

Funder type
University/education

Funder Name
Medizinische Universität Wien

Alternative Name(s)
Medical University of Vienna, MediUni Wien

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Austria

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
01/10/2022

Individual participant data (IPD) sharing plan
All data generated or analysed 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?
Protocol file	version v5.0	16/10/2019	05/09/2020	No	No
Protocol file	version v5.0	16/10/2019	05/09/2020	No	No