ISRCTN67851517 https://doi.org/10.1186/ISRCTN67851517

Evaluation of two protocols for non-surgical treatment of periodontitis

Submission date
30/10/2025

Recruitment status
No longer recruiting

Registration date
26/11/2025

Overall study status
Completed

Last Edited
26/11/2025

Condition category
Oral Health

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

Plain English summary of protocol

Background and study aims
Periodontitis is a chronic inflammatory disease of the gums that leads to bone, soft tissue and tooth loss. Scaling and root planing (SRP) is the basic treatment for periodontitis. Due to the limitations of SRP and the multiple causes of periodontal disease, new methods are being sought to support this treatment. One of them is the local use of local antibiotics such as a tazobactam/piperacillin formulation (Gelcide, MTD, Switzerland). Therefore, the aim of this study was to evaluate periodontal (gum) parameters and take samples of the gingival crevicular fluid around the gums after SRP with and without the application of a local antibiotic to the gum pockets.

Who can participate?
Patients aged over 18 years with periodontitis stage II/III

What does the study involve?
Patients were randomly assigned to two groups:
1. The study group (SRP + local antibiotic application to pockets minimum 5 mm)
2. The control group (SRP)
The study involves clinical examination of the gums and GCF sampling from deep gum pockets.

What are the possible benefits and risks of participating?
The advantage of participating in the study is the possibility of cleaning the gum pockets using mechanical methods or mechanical methods with additional local antibiotic therapy. The risk of participating is similar to that of a routine dental visit.

Where is the study run from?
Medical University of Bialystok (Poland)

When is the study starting and how long is it expected to run for?
June 2020 to June 2022

Who is funding the study?
Medical University of Bialystok (Poland)

Who is the main contact?
Dr Ewa Dolińska, ewa.dolinska@umb.edu.pl

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Ewa Dolińska

ORCID ID
https://orcid.org/0000-0003-3122-4990

Contact details
ul. Waszyngtona 13
Białystok
Poland
15-269
+48 (0)85 7485905
ewa.dolinska@umb.edu.pl

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
SUB/1/NN/22/001/1164

Study information

Scientific Title
Evaluation of two protocols for non-surgical treatment of periodontitis - with or without subgingival antibiotic application

Study objectives
The aim of the study is to compare the clinical effects of a local antibiotic formulation (piperacillin/tazobactam) applied subgingivally to pockets with PD >5 mm after scaling and root planing (SRP) with SRP alone in patients with periodontitis. In addition, gingival crevicular fluid (GCF) will be collected during the study for molecular and microbiological testing.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 23/09/2020, Bioethics Committee Medical University of Bialystok (ul. Jana Kilińskiego 1, Bialystok, 15-089, Poland; +48 (0)85 748 54 07; komisjabioetyczna@umb.edu.pl), ref: APK. 002.271.2020

Study design
Randomized controlled clinical trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Periodontitis

Interventions
Randomisation was performed by tossing a coin before the intervention. Patients were randomly assigned to two groups:
1. The study group (SRP + local antibiotic application to pockets minimum 5 mm)
2. The control group (SRP)

Study group patients were treated by scaling and root planing (SRP) and subsequently, the locally delivered preparation containing tazobactam and piperacillin was applied using a blunt cannula to four selected pockets with PD ≥5 mm.

Intervention Type
Mixed

Primary outcome(s)
1. Pocket depth (PD) measured in mm with periodontal probe PCUNC15 at baseline, 3 and 6 months
2. Clinical attachment level (CAL) measured in mm with periodontal probe PCUNC15 at baseline, 3 and 6 months
3. Gingival recession (GR) measured in mm with periodontal probe PCUNC15 at baseline, 3 and 6 months
4. Number of pockets with PD >=5 mm counted at baseline, 3 and 6 months

Key secondary outcome(s))
Gingival crevicular fluid (GCF) sampled at baseline, 2 weeks, 3 months and 6 months and frozen for future laboratory analysis

Completion date
22/06/2022

Eligibility

Key inclusion criteria
1. Diagnosed periodontitis stage II or III, grade B or C
2. Presence of at least 16 teeth (at least 4 in each quadrant)
3. Presence of at least 4 deep periodontal pockets (PD ≥5 mm)
4. No professional hygiene procedures in the last 6 months

5. No systemic antibiotic therapy in the last 3 months
6. Aged over 18 years
7. Being non-smoker

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Total final enrolment
38

Key exclusion criteria
1. General contraindications to any periodontal therapy
2. Immunosuppression
3. Immunological incompetence
4. Uncontrolled diabetes
5. Pregnancy and breastfeeding
6. Alcohol and/or drug dependence
7. Patient allergic to any antibiotics
8. Patient requiring antibiotic cover prior to periodontal therapy
9. Patient with no opportunity to participate in the programme for 6 months

Date of first enrolment
04/01/2021

Date of final enrolment
19/01/2022

Locations

Countries of recruitment
Poland

Study participating centre

Medical University of Bialystok
Department of Periodontal and Oral Mucosa Diseases
ul. Waszyngtona 13
Bialystok
Poland
15-269

Sponsor information

Organisation
Medical University of Białystok

ROR
https://ror.org/00y4ya841

Funder(s)

Funder type
University/education

Funder Name
Uniwersytet Medyczny w Białymstoku

Alternative Name(s)
Medical University of Bialystok, UMB

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Poland

Results and Publications

Individual participant data (IPD) sharing plan
The data are available on reasonable request from Dr Ewa Dolińska (ewa.dolinska@umb.edu.pl)

IPD sharing plan summary
Available on request