

Non-surgical therapy in addition to three or seven days of amoxicillin and metronidazole treatment in patients with severe gum infection (periodontitis)

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| Submission date 22/02/2021 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol |
| Registration date 24/02/2021 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 30/03/2023 | Condition category Oral Health | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol

Background and study aims

Periodontitis is a severe gum infection that can lead to tooth loss and other serious health complications. Periodontitis, also called gum disease, is a serious gum infection that damages the soft tissue and, without treatment, can destroy the bone that supports your teeth. Studies evaluating the clinical, microbiological and immunological efficacy of a short-term administration of amoxicillin (AMX) and metronidazole (MET) for aggressive periodontitis are scarce.

The aim of the study is to evaluate the clinical, immunological, microbiological effect after 3, 6 and 12 months following non-surgical periodontal therapy in conjunction with the adjunctive use of AMX+MET administered for 3 or 7 days in patients with stage III to IV grade C periodontitis (aggressive periodontitis).

Who can participate?

Adults over 18 years with untreated aggressive periodontitis, that are otherwise healthy.

What does the study involve?

After receiving treatment for periodontitis using the usual methods, participants will be randomly allocated to receive either 3 or 7 days of antibiotics to aid recovery. Participants will be followed up for 12 months.

What are the possible benefits and risks of participating?

The patients receive periodontal treatment, periodontal inflammation will be eliminated and diseases progression will be stopped.

Possible side-effects are those related to antibiotic intake: gastro-intestinal disorders, allergic reactions, headache, taste disorders, vertigo; sideeffects related to non-surgical periodontal treatment: bleeding, pain, tooth hypersensitivity.

Where is the study run from?

The Clinic for Prosthodontics, University Iuliu Hatieganu Cluj-Napoca (Romania)

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

March 2015 to December 2019

Who is funding the study?

Investigator initiated and funded

Who is the main contact?

Dr. Raluca Cosgarea

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Protocol serial number

398/3.7.2015

Study information

Scientific Title

Short-term systemic antibiotics in periodontal treatment in patients suffering from aggressive periodontitis

Acronym

AB-AgP

Study objectives

The non-surgical periodontal therapy (performed within 24 hours) in conjunction with adjunctive administration of systemic amoxicillin and metronidazole for a period of either 3 or 7 days in patients with severe aggressive periodontitis provide comparable clinical results.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 02/07/2015, Ethical Committee of the Faculty of Medicine and Pharmacy of Iuliu-Hatieganu University Cluj-Napoca (Str. Victor Babes nr 8, Cluj-Napoca, Romania; +40-264-597256; etica.cercetare@umfcluj.ro), ref: 398/3.7.2015

Study design

Prospective randomized controlled clinical trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Non-surgical treatment of aggressive periodontitis

Interventions

- All patients receive oral hygiene instructions and professional supragingival cleaning sessions until a full-mouth plaque score (FMPS) $\leq 25\%$ is obtained.
- Thereafter, subgingival debridement (SD) is performed within 2 consecutive days at all sites with PD ≥ 4 mm with Gracey curets and ultrasonic instruments;
- After SD, patients are instructed to rinse for the following 2 weeks with chlorhexidine digluconate 0.2% solution and brush their teeth with chlorhexidine-digluconate toothpaste.
- At the end of the last SD session, patients are allocated to one of the two treatment groups:
Amoxicillin + metronidazole both 500 mg three times a day (TID) for 3 days (Group A)
Amoxicillin + metronidazole both 500 mg TID for 7 days (Group B)

A computer-generated randomisation list (block-randomisation) is used.

The following clinical parameters are assessed at baseline, at 3, 6 and 12 months: probing pocket depths (PPD), clinical attachment level (CAL), furcation involvement (FI), bleeding on probing (BOP), full mouth plaque scores (PCR). Additionally, subgingival samples for microbiological [A. actinomycetemcomitans (A.a.), P.gingivalis (P.g.), T.forsythia (T.f.), P.intermedia (P.i.), T.denticola (T.d.), P.micra (P.m.), F.alocis (F.a.), C.rectus (C.r.)] and inflammatory markers (IL-1 β , IL-8, IL-10, MMP-8) analyses will be performed.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Amoxicillin, metronidazole

Primary outcome(s)

Number of residual deep sites with probing depth ≥ 6 mm at 6 and 12 months

Key secondary outcome(s)

Measured at baseline, 6 and 12 months:

1. Probing pocket depths measured using patient records
2. Clinical attachment level measured using patient records
3. Bleeding on probing measured using patient records
4. Full-mouth plaque scores measured using patient records
5. Quantitative changes in investigated bacteria and inflammatory markers (sterile paper points were introduced in periodontal pockets, and then by real-time PCR and analysed using metagenome shotgun sequencing + metagenomic microbiome sequencing (for microbiology) and by ELISA test (for immunology))

Completion date

01/12/2019

Eligibility**Key inclusion criteria**

1. Age 18 - 36 years
2. ≥ 12 natural teeth present in the oral cavity distributed in all four quadrants
3. Clinical signs of stage III and IV grade C Periodontitis (Tonetti et al 2018) (previous aggressive periodontitis) (Armitage. 1999): interdental CAL loss ≥ 5 mm, tooth loss due to periodontitis \leq or ≥ 4 teeth, min. one PD ≥ 6 mm in each quadrant
4. Radiographic signs of stage III and IV grade C Periodontitis (Tonetti et al 2018): radiographic bone loss to middle or apical third of the root, vertical bone loss ≥ 3 mm, % bone loss/age > 1 , or ≥ 2 mm bone loss in the past 5 years when older x-rays are present
5. Full-mouth plaque scores (FMPS) $\leq 25\%$ (O'Leary et al. 1972)
6. Systemically healthy, i.e. absence of a known condition that may influence the severity or progression of periodontal disease (e.g. Down syndrome, HIV, diabetes mellitus type 1 and 2)
7. No head and neck radiation therapy
8. No infectious or heart diseases that need prophylactic administration of antibiotics before dental treatment
9. No liver disease

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Total final enrolment

50

Key exclusion criteria

1. Non-surgical periodontal therapy within the previous 12 months
2. Systemic or local use of antibiotics within the previous 6 months
3. Any type of systemic medication within the previous 6 months
4. Pregnancy or lactation
5. Smoking >10 cigarettes/day

Date of first enrolment

01/09/2015

Date of final enrolment

01/09/2018

Locations**Countries of recruitment**

Romania

Study participating centre

Policlinic of prosthodontics, University Iuliu-Hatieganu Cluj-Napoca

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400506

Sponsor information**Organisation**

Iuliu Hațieganu University of Medicine and Pharmacy

ROR

<https://ror.org/051h0cw83>

Organisation

University of Bern

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

IPD sharing plan summary

Available on request

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---------|--------------|------------|----------------|-----------------|
| Results article | results | 21/08/2022 | 30/03/2023 | Yes | No |
| Participant information sheet | | | 01/03/2021 | No | Yes |
| Protocol file | | 01/07/2015 | 01/03/2021 | No | No |