

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

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

**EudraCT/CTIS number**

Nil known

**IRAS number**

**ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

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

## **Secondary study design**

Randomised controlled trial

## **Study setting(s)**

Hospital

## **Study type(s)**

Treatment

## **Participant information sheet**

See additional file (in Romanian) ISRCTN55637591\_PIS (added 01/03/2021)

## **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  $\geq 4$  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 $\beta$ , 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 measure**

Number of residual deep sites with probing depth  $\geq 6$  mm at 6 and 12 months

### **Secondary outcome measures**

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))

### **Overall study start date**

10/03/2015

### **Completion date**

01/12/2019

## **Eligibility**

### **Key inclusion criteria**

1. Age 18 - 36 years
2.  $\geq 12$  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  $\geq 5$  mm, tooth loss due to periodontitis  $\leq$  or  $\geq 4$  teeth, min. one PD  $\geq 6$  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  $\geq 3$  mm, % bone loss/age  $> 1$ , or  $\geq 2$  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

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

50

**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**

Str. Clinicilor nr 32

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# Sponsor information

## Organisation

Iuliu Hațieganu University of Medicine and Pharmacy

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## Sponsor type

University/education

## Website

<http://www.umfcluj.ro/en/>

## ROR

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

## Organisation

University of Bern

## Sponsor details

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## Sponsor type

University/education

## Website

<http://www.unibe.ch/eng/>

# Funder(s)

## Funder type

Other

## Funder Name

Investigator initiated and funded

# Results and Publications

## Publication and dissemination plan

2-3 planned publications in high-impact peer-reviewed journals and presentation at congresses.

## Intention to publish date

01/03/2021

## 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?
<a href="#">Participant information sheet</a>			01/03/2021	No	Yes
<a href="#">Protocol file</a>		01/07/2015	01/03/2021	No	No
<a href="#">Results article</a>	results	21/08/2022	30/03/2023	Yes	No