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# Comparing 3 versus 7 days systemic administration of Amoxicillin (AMX) and Metronidazole (MET) in severe chronic periodontitis patients

**Submission date**
09/06/2015

**Recruitment status**
No longer recruiting

**Registration date**
16/06/2015

**Overall study status**
Completed

**Last Edited**
10/07/2023

**Condition category**
Oral Health

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

## Plain English summary of protocol

Background and study aims
Chronic periodontitis is an inflammatory disease mainly initiated by bacteria residing in biofilms at and below the gingival margins. It affects the tissues surrounding the teeth involving progressive loss of the tooth supporting structures. Initial treatment includes the removal of bacterial deposits from the tooth structures through mechanical cleaning called scaling and root planning (SRP). Because bacteria are found in areas that hard to reach, SRP does not remove all bacteria and antibacterial agents (antibiotics and antiseptics) are also used. The aim of the present study is to evaluate the clinical outcomes following non-surgical periodontal therapy (performed within 24 hours) in conjunction with adjunctive Amoxicillin (AMX) and Metronidazole (MET) administered systemically for 3 and 7 days in patients with severe chronic periodontitis.

Who can participate?
Adults over 30 with severe chronic periodontitis

What does the study involve?
Participants are randomly allocated to one of three treatment groups:
- control group: non-surgical periodontal treatment (SRP) within 24 hours and dummy pills (3 times daily) for 7 days
- antibiotic group 1: SRP within 24h, then the following 3 days Amoxicilline and Metronidazole (both 500 mg 3 times daily), and then for another 4 days dummy pills (3 times daily)
- antibiotic group 2: SRP within 24h, then the following 7 days Amoxicilline and Metronidazole (both 500 mg 3 times daily)

What are the possible benefits and risks of participating?
This is a low risk study. All participants receive periodontal treatment.

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

When is the study starting and how long is it expected to run for?
January 2012 to June 2015

Who is funding the study?
University of Medicine and Pharmacy "IUliu Hatieganu" Cluj Napoca (Romania)

Who is the main contact?
Dr Raluca Cosgarea

# Contact information

### Type(s)
Scientific

### Contact name
Dr Raluca Cosgarea

### Contact details
Str. Clinicilor nr 32
Cluj-Napoca
Romania
400506

# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
514/09.01.2012

# Study information

### Scientific Title
A randomized controlled clinical study on non-surgical periodontal treatment in conjunction with 3 versus 7 days systemic administration of Amoxicillin and Metronidazole in severe chronic periodontitis patients

### Acronym
AMX-MET

### Study objectives
The null hypothesis to be tested in this RCT is “no difference in the treatment effect regarding the difference in the number of deep pockets (PD≥ 6 mm) for the systemic use of Amoxicillin and Metronidazole administered for 3 days compared with the administration of the same antibiotics for 7 days adjunctive to SRP”.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Ethics Committee (Comisia de etica) of the University of Medicine and Pharmacy "Iuliu Hatieganu", Cluj-Napoca, Romania, 20/01/2012, ref 514/09.01.2012

## Study design
Single centre placebo controlled double masked randomized clinical interventional 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 the contact details below to request a patient information sheet

## Health condition(s) or problem(s) studied
Severe chronic periodontitis

## Interventions
All patients received oral hygiene instructions and cleanings.
Three treatment procedures were performed according to a computer generated randomisation list:
- control group: non-surgical periodontal treatment (scaling and root planing SRP) within 24 hours and placebo pills (3 times daily) for 7 days
- antibiotic group 1: SRP within 24h, then the following 3 days Amoxicilline (AMX) and Metronidazole (MET)- both for 500 mg (3 times daily), and then for another 4 days placebo pills (3 times daily)
- antibiotic group 2: SRP within 24h, then the following 7 days Amoxicilline (AMX) and Metronidazole (MET)- both for 500 mg (3 times daily)
All patients rinsed their mouths for the following 2 weeks with chlorhexidine digluconate 0.2% solution and used tooth paste with 0.2% chlorhexidine digluconate.
Clinical periodontal parameters (probing pocket depth, clinical attachment level, bleeding on probing, furcation involvement, full-mouth plaque score -FMPS-, gingival bleeding index -GBI), sulcus fluid for microbiological and immunological determinations were determined at baseline, at 2 weeks, at 3, 6 and 12 months after treatment.
Patients were asked about their compliance for the pills intake and adverse effects.

## Intervention Type
Drug

### Phase
Not Applicable

### Drug/device/biological/vaccine name(s)
Amoxicillin, metronidazole

### Primary outcome measure
Difference of the number of sites per patient with pocket depth ≥ 6 mm between baseline and 6 months

### Secondary outcome measures
Secondary variables were changes in: probing pocket depth, clinical attachment level, bleeding on probing, furcation involvement, full-mouth plaque score -FMPS-, gingival bleeding index -GBI, number of sites per patient with PD ≥ 6 mm, number of sites per patient ≥ 5 mm, bacterial load of Aggregatibacter actinomycetemcomitans, Porphyromonas gingivalis, Tanerella Forsythia, Treponema denticola, Prevotella intermedia, levels of IL-10. IL-1ß, TNF-alpha, MMP-8.

### Overall study start date
01/01/2012

### Completion date
01/06/2015

## Eligibility

### Key inclusion criteria
1. >30 years
2. Diagnosis of severe chronic periodontitis (Armitage 1999)
3. ≥ 12 natural teeth
4. ≥ 1 site/quadrant with pocket depth ≥ 6mm
5. Full-mouth plaque scores ≤ 25% (O`Leary 1972)
6. systemically healthy
7. No allergies for penicillin or 5-nitroimidazole derivates

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
30 Years

### Sex
Both

### Target number of participants
102 patients

### Total final enrolment

102

### Key exclusion criteria
1. Non-surgical periodontal therapy within 12 months
2. Systemic/local antibiotics within the previous 3 months
3. Medication that could interact with amoxicilline or metronidazole
4. Pregnancy/lactation

### Date of first enrolment
30/01/2012

### Date of final enrolment
30/01/2014

## Locations

### Countries of recruitment
Romania

### Study participating centre
**Clinic for Prosthodontics, University of Medicine and Pharmacy "Iuliu Hatieganu"**
Str. Clinicilor nr 32
Cluj-Napoca
Romania
4000506

## Sponsor information

### Organisation
Department of prosthodontics, University of Medicine and Pharmacy "Iuliu Hatieganu"

### Sponsor details
Str. Cliniclor nr 32
Cluj Napoca
Romania
4000506

### Sponsor type
Hospital/treatment centre

### ROR
https://ror.org/051h0cw83

# Funder(s)

### Funder type
University/education

### Funder Name
Philipps University of Marburg (Germany)

# Results and Publications

### Publication and dissemination plan
We intend to publish our results in highly ranked international dental journals.
Preliminary data and final results of this trial have already been presented at several international congresses:
- annual meeting of the German Society of Periodontology where it was awarded with the best ORL presentation for clinical research 2014
- EuroPerio 2015 where it was selected between the first 3 studies for the Jaccard Prize Competition
- CED-Continental Division of the IADR-International Association for Dental Research Oct 2014 Antalya.

### Intention to publish date
31/12/2015

### 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 | | 23/06/2016 | 26/11/2021 | Yes | No |
| Results article | | 29/06/2017 | 10/07/2023 | Yes | No |
| Results article | | 01/10/2020 | 10/07/2023 | Yes | No |