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

Submission date
22/02/2021

Recruitment status
No longer recruiting

Registration date
24/02/2021

Overall study status
Completed

Last Edited
30/03/2023

Condition category
Oral Health

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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 inflamation 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 hypersinsetivity.

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?
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Contact information

Type(s)
Scientific

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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) ≤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. actinomicetemcomitans (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-1β, 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 ≥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. ≥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 die to periodontitis ≤ 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 appical third of the root, vertical bone loss ≥3mm, % 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) ≤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

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Sponsor type
University/education

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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?
Participant information sheet			01/03/2021	No	Yes
Protocol file		01/07/2015	01/03/2021	No	No
Results article	results	21/08/2022	30/03/2023	Yes	No