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Adjunctive antimicrobial therapy of Periodontitis: long-term effects on disease progression and oral microbiological colonisation

Submission date
09/03/2007

Recruitment status
No longer recruiting

Registration date
30/03/2007

Overall study status
Completed

Last Edited
11/04/2019

Condition category
Oral Health

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

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.abparo.de

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00707369

Secondary identifying numbers
EH 365/1-1

Study information

Scientific Title
Adjunctive antimicrobial therapy of Periodontitis: long-term effects on disease progression and oral microbiological colonisation

Acronym
ABPARO

Study objectives
Please note that as of 01/08/2008 this record has been updated. All updated can be found in the relevant field under the above update date. Please note that the anticipated start and end dates of this trial have also been updated. The previous dates were as follows:
Previous anticipated start date: 01/09/2007
Previous anticipated end date: 01/11/2011
Please also note that the acronym has been updated to the above; the previous acronym was 'AP'.

Current hypothesis as of 01/08/2008:
The administered empiric adjunctive antibiotic therapy reduces about one half of the proportion of sites with attachment loss compared to subgingival debridement alone over a 27.5-month period in a statistical and clinical significant manner.

Previous hypothesis:
The administered empiric adjunctive antibiotic therapy reduces about one half of the proportion of sites with attachment loss compared to subgingival debridement alone over a 26-month period in a statistical and clinical significant manner.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received from the local ethics committee (Ethikkommission der Aerztekammer Westfalen-Lippe und der Med. Fakultaet der Westfaelischen Wilhelms-Universtitaet Muenster) on the 21st December 2006 (ref: 2006-474-f-A).

Study design
Double-blind, parallel group, randomised, placebo-controlled, multi-centre, phase IV efficacy study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Patient information can be found at: http://www.abparo.de/patienten.shtml

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

Interventions
Experimental intervention:
Mechanical debridement plus 500 mg amoxicillin and 400 mg metronidazole three times daily for seven days. Supportive periodontal therapy in three-month intervals.

Control intervention:
Mechanical debridement alone. Supportive periodontal therapy in three-month intervals.

Duration of intervention per patient:
27.5 months. The control intervention represents the gold standard in periodontal therapy.

There are no additional risks of adverse effects for the participating control group patients that go beyond the risks associated with periodontal standard care. The major risk for both groups is associated with the local anaesthesia (cardiac or anaphylactic reactions, trauma of the lingual and /or lower mandibular nerve, and infections). A minor adverse effect of subgingival debridement might be root hypersensitivity. For the test group patients, the administration of systemic antibiotics (allergic reaction, gastrointestinal discomfort, pseudomembranous colitis, neurological disorders, urticaria, and drug interactions) is an additional risk. However, severe adverse effects caused by the intake of amoxicillin plus metronidazole are extremely rare.

The expected benefits are a reduction of the intraoral periodontal pathogenic microflora and due to that, a decrease of the amount of sites losing tooth supporting tissues. We expect that the adjunctive antibiotic therapy reduces further tooth loss and will improve the patients quality of life.

Sponsor amended as of March 2009 to that of below; initial sponsor information at the time of registration: Westfälische Wilhelms University of Muenster (Germany)

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Amoxicillin and metronidazole

Primary outcome measure
Percentage of sites showing attachment loss greater than or equal to 1.3 mm over a 27.5-months period.

Secondary outcome measures
1. Subjective perception of treatment outcome
2. Attachment gain
3. Pocket probing depths
4. Bleeding on probing
5. Full mouth plaque score
6. Microbial colonisation dynamic

All secondary outcomes will be measured at 3.5, 15.5, and 27.5 months after therapy. At 9.5 and 21.5 no microbiological samples will be taken, and at 6.5 months, only microbiological samples will be taken.

Overall study start date
01/07/2008

Completion date
01/01/2012

Eligibility

Key inclusion criteria
Current inclusion criteria as of 01/08/2008:
Subjects selected for the study must meet the following inclusion criteria:
1. Periodontal Screening Index (PSI) of IV in at least one sextant
2. Range from 18 to 75 years of age with clinical and radiographic signs of moderate (Clinical Attachment Loss [CAL] of 3 to 4 mm) to severe (CAL 5 mm or more) chronic or aggressive periodontitis
3. At least 10 natural teeth in situ
4. Pocket Probing Depths (PPDs) of greater than or equal to 6 mm at a minimum of four teeth
5. Willingness to participate and to be available at all times required for participation
6. Willingness to abstain from using antimicrobial mouth-rinses during the study except for those explicitly prescribed
7. The informed consent signed by the patient
8. Sufficient knowledge of German language

Previous inclusion criteria:
Subjects selected for the study must meet the following inclusion criteria:
1. Periodontal Screening Index (PSI) of IV in at least one sextant
2. Range from 18 to 75 years of age with clinical and radiographic signs of moderate (Clinical Attachment Loss [CAL] of 3 to 4 mm) to severe (CAL 5 mm or more) chronic or aggressive periodontitis
3. At least 10 natural teeth in situ
4. Pocket Probing Depths (PPDs) of greater than or equal to 6 mm at a minimum of four teeth
5. No professional periodontal therapy during the six months preceding the baseline clinical evaluation, and willingness to participate and to be available at all times required for participation

6. Willingness to abstain from using antimicrobial mouth-rinses during the study except for those explicitly prescribed
7. The informed consent signed by the patient

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
500

Key exclusion criteria
Current exclusion criteria as of 01/08/2008:
1. Report themselves confirmed or assumed allergies or hyper-sensitive skin reactions against amoxicillin, metronidazol or lactose, or in parents or siblings
2. Have Downs syndrome
3. Known acquired immune deficiency syndrome (AIDS)/human immunodeficiency virus (HIV)
4. Regularly take drugs that may affect the periodontal conditions, e.g. phenytoine, nifedipine, and/or steroid drugs
5. Professional periodontal therapy during the six months preceding the baseline clinical evaluation
6. Require antibiotic treatment for dental appointments
7. Are undergoing or require extensive dental or orthodontic treatment
8. Are pregnant or breastfeeding
9. Have rampant caries
10. Have any oral or extra-oral piercing in or around the oral cavity with ornaments or accessory jewellery
11. Are dental students or dental professionals
12. Have participated in a clinical dental trial in the six months preceding the study
13. Cognitive deficits

Previous exclusion criteria:
1. Report themselves confirmed or assumed allergies or hyper-sensitive skin reactions against amoxicillin, metronidazole or lactose, or in parents or siblings
2. Have Downs syndrome, known Acquired Immune Deficiency Syndrome (AIDS)/Human Immunodeficiency Virus (HIV) or deregulated diabetes type one or two as determined by assessment of erythrocyte HbA1c levels (more than 6.5%)
3. Regularly take drugs that may affect the periodontal conditions, e.g. phenytoine, nifedipine, and/or steroid drugs
4. Require antibiotic treatment for dental appointments
5. Are undergoing or require extensive dental or orthodontic treatment
6. Are pregnant or breastfeeding
7. Have rampant caries

8. Have any oral or extra-oral piercing in or around the oral cavity with ornaments or accessory jewellery
9. Are dental students or dental professionals, or have participated in a clinical dental trial in the six months preceding the study
10. Cognitive deficits
11. Insufficient knowledge of German language

Date of first enrolment
01/07/2008

Date of final enrolment
01/01/2012

Locations

Countries of recruitment
Germany

Study participating centre
University of Münster
Münster
Germany
48149

Sponsor information

Organisation
University Hospital Muenster (Germany)

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Sponsor type
University/education

Website
http://klinik.uni-muenster.de/

ROR
https://ror.org/01856cw59

Funder(s)

Funder type
Research organisation

Funder Name
German Research Foundation (Deutsche Forschungsgemeinschaft) (Germany) (ref: EH 365/1-1)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2015	19/02/2019	Yes	No
Results article	results	01/02/2019	19/02/2019	Yes	No
Results article	sub-analysis results	01/10/2016	19/02/2019	Yes	No