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Comparison between two chlorhexidine gels for treatment of chronic periodontitis

Submission date
30/06/2014

Recruitment status
No longer recruiting

Registration date
31/07/2014

Overall study status
Completed

Last Edited
17/12/2020

Condition category
Oral Health

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

Plain English summary of protocol

Background and study aims
Long-term gum disease (chronic periodontitis) is the inflammation of the tissues around the teeth caused by dental plaque and calculus (tartar). The first phase of treatment usually consists of removal of irritants by a procedures such as scaling and root planing. Disinfectant substances may be additionally used during the procedure and are routinely recommended for the home care after such a procedure. The aim was to evaluate the effect of a new hydrophobic gingiva-adhering gel, in comparison with a standard commercially-available 1% chlorhexidine digluconate water-soluble gel, in non-surgical therapy of moderate long-term gum disease, after full mouth scaling and root planing.

Who can participate?
Adults aged 40-65 years, suffering from a long-term gum disease can take part.

What does the study involve?
The participants were randomly allocated to one of two groups. The test group received the hydrophobic gel for gentle rubbing on the gum (gingiva), once every second day for 14 days. The control group received the standard water-soluble chlorhexidine gel, daily, twice a day.

What are the possible benefits and risks of participating?
Enrolled participants will gain a complete non-surgical treatment of periodontitis. There were no side effects of treatment.

Where is the study run from?
1. The Victor Babes University of Medicine and Pharmacy of Timisoara (Romania)
2. Iuliu Hatieganu University of Medicine of Cluj (Romania)
3. University of Leipzig (Germany)

When is the study starting and how long is it expected to run for?
The study took place between January 2010 and May 2013.

Who is funding the study?
lege artis Pharma, Dettenhausen, Germany.

Who is the main contact?
Prof Stefan-Ioan Stratul
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Contact information

Type(s)
Scientific

Contact name
Prof Stefan Ioan Stratul

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Additional identifiers

Protocol serial number
1/2010

Study information

Scientific Title
Evaluation of a hydrophobic gel adhering to the gingiva in comparison with a standard water soluble 1% chlorhexidine gel after full mouth scaling and root planing in patients with moderate chronic periodontitis: a randomized clinical trial

Acronym
durimplant

Study objectives
The study tested the null hypothesis that there are no differences in the outcomes regarding the probing depth, attachment level, plaque indices, bleeding on probing, as well as subgingival microbiota and PMN-characterizing enzymes during the first 6 months after scaling and root planing.

Ethics approval required
Old ethics approval format

Ethics approval(s)

1. Ethics Committees of the Faculty of Medicine of the University of Leipzig, ref. approval No.190 2009
2. Victor Babes University of Medicine and Pharmacy of Timisoara, ref. 12/14.12.2009

Primary study design
Interventional

Study design
Randomized parallel controlled double-blind trial

Study type(s)
Treatment

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

Interventions
Full mouth scaling and root planing, application of a novel hydrophobic gingiva-adhering chlorhexidine-based gel with complex composition vs a standard commercially available 1% chlorhexidine digluconate water-soluble gel.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Clinical measurements and photographs were taken at baseline and at follow-up post-operatory 3 and 6 months for both primary and secondary outcome measures.
1. Clinical attachment level
2. Frequency of detection of periodontopathogenic bacteria
3. Enzymatic activity of neutrophil elastase and myeloperoxidase

Key secondary outcome(s)
1. Pocket depth
2. Gingival recession
3. Plaque indices

Completion date
31/05/2013

Eligibility

Key inclusion criteria
1. Age between 40 65 years old,
2. Moderate chronic periodontitis (two or more interproximal sites with ≥ 4 mm clinical CAL [not on the same tooth] or two or more interproximal sites with ≥ 5 mm PD, also not on the same tooth [according to the CDC-AAP definition])

3. At least 20 teeth present in the mouth
4. No periodontal therapy during the last 2 years
5. No antibiotic or anti-inflammatory drugs intake during the last 6 months before baseline examination
6. Absence of fixed or removable prosthesis
7. Good general health

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
34

Key exclusion criteria
1. Either pregnant or nursing
2. Any diseases with influence on the periodontal diseases
3. Allergies to the components of the products used in the study

Date of first enrolment
01/01/2010

Date of final enrolment
31/05/2013

Locations

Countries of recruitment
Romania

Study participating centre
Victor Babes University of Medicine and Pharmacy Timisoara
Timisoara
Romania
300041

Sponsor information

Organisation
lege artis Pharma GmbH + Co. KG (Germany)

Funder(s)

Funder type
Industry

Funder Name
lege artis Pharma GmbH + Co. KG, Dettenhausen, Germany

Results and Publications

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	01/02/2017	17/12/2020	Yes	No