

# Comparison between two chlorhexidine gels for treatment of chronic periodontitis

<b>Submission date</b> 30/06/2014	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 31/07/2014	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 17/12/2020	<b>Condition category</b> Oral Health	<input type="checkbox"/> 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  
sbs@online.ro

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof Stefan Ioan Stratul

**Contact details**  
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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
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

**Study design**

Randomized parallel controlled double-blind trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Other

**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**

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 measure**

Clinical measurements and photographs were taken at baseline and at follow-up post-operative 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

**Secondary outcome measures**

1. Pocket depth
2. Gingival recession
3. Plaque indices

**Overall study start date**

01/01/2010

**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  $\geq 4$  mm clinical CAL [not on the same tooth] or two or more interproximal sites with  $\geq 5$  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

**Age group**

Adult

**Sex**

Both

**Target number of participants**

32 calculated, 34 included

**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)

## Sponsor details

Breitwasenring 1

Dettenhausen

Germany

D-72135

## Sponsor type

Industry

## Website

<http://www.legeartis.de>

# Funder(s)

## Funder type

Industry

## Funder Name

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

# 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?
<a href="#">Results article</a>	results	01/02/2017	17/12/2020	Yes	No