Trial Description

Title

Clinical research on photodynamic therapy of gingival hypertrophy in orthodontic patients

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

Patients with orthodontic appliances, like braces and bands, have a higher risk to suffer from gingival enlargement and gingival inflammation due to complicated dental hygiene. To eliminate those bacteria, which cause the gingival enlargement we would like to use photodynamic therapy (PDT). Therefore we are going to apply a blue photosensitizer, which marks the bacteria, into the gingival pocket. Afterwards the bacteria are going to be eliminated through exposure with athermic laser light.

Brief Summary in Scientific Language

The subject and methods for our clinical research are planned as followed. We would like to examinate 29 patients, who suffer from gingival hypertrophy, at least on their 1st molar and 2nd incisors, due to orthodontic appliances (bands, braces). We are going to test the PDT twice (interval of 1 week) on the test side (split-mouth-design and cross-over-design) with the HELBO laser from Bredent Group. Before treating and afterwards we will gain parameters on the test and control side through evaluating the gingival bleeding (modified Saxer & Mühlemann modified papillary bleeding index), measuring the distance between the highest point of the gingival enlargement and a certain point on the orthodontic appliance. As an accompanying measure we will take samples with paper points from the hypertrophy to undertake PCR and hopefully gain a significant reduction of periodontal bacteria.

Organizational Data

- DRKS-ID: **DRKS00006292**
- Date of Registration in DRKS: **2014/09/01**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **EA 2/013/14 , Ethik-Kommission der Charité - Universitätsmedizin Berlin-**

Secondary IDs

Health condition or Problem studied

- ICD10: **K06.1 - Gingival enlargement**

Interventions/Observational Groups

- Arm 1: **Arm 1: Test side**
  29 patients, who suffer from gingival hypertrophy due to orthodontic appliances (bands, braces) are going to be treated with the Photodynamic Therapy. After a professional tooth cleaning we are going to test the Photodynamic Therapy with the HELBO laser twice (interval of 1 week) on the test side. To avoid a reinfection on the nearby teeth, Photodynamic Therpay is going to be applied on all teeth of the test side. We will gain the parameters only from the 1st molars and 2nd incisors.
  The samples (supragingival, subgingival plaque) for the PCR will be taken on the test and control side from the 1st molars in the upper jaw and the 2nd incisors in the lower jaw. In addition to that, we will take a subgingival sample from the upper canine of the 1st quadrant palatinal. It serves as a comparative sample for a healthy tooth because we can assume there is no hyperthropy at an upper canine at all.
  Which side is the test or controle side, we can find out from the randomisation list. The therapy will be done in the 1st quadrant and 3rd quadrant or in the 2nd and 4th quadrant.

- Arm 2: **Arm 2: Control side**
  On the same 29 patients the opposite from the test side is the control side. The control side will get a professional tooth cleaning but no treatment with Photodynamic Therapy. The parameters from the control side will be gained only from the 1st molars and 2nd incisors.
  The samples (subgingival and supragingival plaque) for the PCR will be taken on the test and control side from the 1st molars in the upper jaw, from the canine of the 1st quadrant and the 2nd incisors in the lower jaw.

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
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Study Type: **Interventional**

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Allocation: **Randomized controlled trial**

Blinding: **[---]***

Who is blinded: **assessor**

- Control: **Control group receives no treatment**
- Purpose: **Treatment**
- Assignment: **Crossover**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

The primary outcome should be a reduction of the gingival hypertrophy and the gingival bleeding. Therefore data will be gained through parameters (measuring the distance between the highest point of the gingival enlargement and a certain point on the orthodontic appliance and evaluating the modified papillary bleeding index) before, during and at the end of the study.

Secondary Outcome

The secondary outcome should be a reduction of periodontal bacteria. Therefore data will be gained through PCR befor, during and at the end of the study.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Abteilung für Kieferorthopädie, Orthodontie und Kinderzahnmedizin, Berlin**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2014/11/10**
- Target Sample Size: **29**
- Monocenter/Multicenter trial: **Monocenter trial**

Planned/Actual: **Actual**

(Anticipated or Actual) Date of First Enrollment: **2014/11/10**

Target Sample Size: **29**

Monocenter/Multicenter trial: **Monocenter trial**

- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **10 Years**
- Maximum Age: **60 Years**

Additional Inclusion Criteria

Every patient, who suffers from gingival hypertrophy at least on the 1st molars and 2nd incisors, due to orthodontic appliances (bands, braces) is able to participate in our clinical trial.
It's necessary that the orthodontic treatment
holds up for at least 9 more weeks.
Compliance and reliability are preconditions.
Patients, who are under age, need an agreement from their legal guardian.

Exclusion criteria

1. Patient and/or legal guardian does not want to participate the clinical trial
2. Patient is not peridontal healthy when he starts orthodontic treatment (peridontal screening index is bigger than 1)
3. Orthodontic treatment does not hold up 9 more weeks
4. General diseases for example leukemia, hereditary gingival fibromatosis etc. and physically or mentally disabled persons
5. Pregnant women
6. Antibiosis in the last 4 weeks before or during the study
7. Medication with drugs, which may induce gingival hypertrophy
8. Antibacterial or antiseptic mouth wash or ointment frequently used

Addresses

- **Primary Sponsor**

  CharitéCentrum 3 für Zahn-, Mund und KieferheilkundeAbteilung für Kieferorthopädie, Orthodontie und Kinderzahnmedizin
  Mr. Professor Paul-Georg Jost-Brinkmann
  Aßmannshauser Str. 4-6

Primary Sponsor

ChariteCentrum 3 für Zahn-, Mund und KieferheilkundeAbteilung für Kieferorthopädie, Orthodontie und Kinderzahnmedizin
Mr. Professor Paul-Georg Jost-Brinkmann
Aßmannshauser Str. 4-6
14197 Berlin
Germany

Telephone: **0049 30 450 562 521**
Fax: **0049 30 450 562 952**
E-mail: **paul-g.jost-brinkmann at charite.de**
URL: **http://kieferorthopaedie.charite.de/**

■ **Contact for Scientific Queries**

ChariteCentrum 3 für Zahn-, Mund- und Kieferheilkunde Abteilung für Kieferorthopädie, Orthodontie und Kinderzahnmedizin
Mr. Prof. Dr. Paul-Georg Jost-Brinkmann
Aßmannshauser Str. 4-6
14197 Berlin
Germany

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Fax: **0049 30 450 562 952**
E-mail: **paul-g.jost-brinkmann at charite. de**
URL: **http://kieferorthopaedie.charite.de/**

■ **Contact for Public Queries**

Charite Centrum 3 für Zahn-, Mund- und Kieferheilkunde
Ms. Rana Manjah
Aßmannshauser Str. 4-6
14197 Berlin
Germany

Telephone: **0049 176 63110990**
Fax: **[---]***
E-mail: **rana139 at googlemail.com**
URL: **[---]***

Sources of Monetary or Material Support

■ **Institutional budget, no external funding (budget of sponsor/PI)**

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Status

- Recruitment Status: **Recruiting ongoing**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

** This entry means the parameter is not applicable or has not been set.*

**** This entry means that data is not displayed due to insufficient data privacy clearing.*