

Trial Description

Title

Use of the bioluminescence technology to monitor active caries lesions - A clinical study

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

Background and objective: In addition to the visual control of caries extent and activity, digital procedures can be used for further diagnostic on occlusal surfaces. Recently, an intraoral device has been introduced that uses the so-called bioluminescence technology and can digitally visualize active caries lesions on the occlusal surface of teeth. The aim of this study was to evaluate the correlation between visual assessment and bioluminescence over a time period.

Brief Summary in Scientific Language

Background and objective: In addition to the visual detection of initial and moderate caries lesions and activity assessment digital technologies can be used to subjectify the findings on occlusal surfaces. Recently, an intraoral device has been introduced that uses the bioluminescence technology in order to digitally visualize active caries lesions on the occlusal surface of teeth. The aim of this study was to evaluate the correlation between visual assessment and bioluminescence measurements and to monitor the findings.

Do you plan to share individual participant data with other researchers?

No

Description IPD sharing plan

The study protocol is designed specifically for the location, so there is no relevance to making the study protocol available.

Organizational Data

- DRKS-ID: **DRKS00020123**
- Date of Registration in DRKS: **2019/12/03**



DRKS-ID: **DRKS00020123**

Date of Registration in DRKS: **2019/12/03**

- 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.: **156/19** , **Ethik-Kommission des Fachbereichs Medizin der Philipps-Universität Marburg**

Secondary IDs

Health condition or Problem studied

- ICD10: **K02.0 - Caries limited to enamel**
- ICD10: **K02.1 - Caries of dentine**

Interventions/Observational Groups

- Arm 1: **Visit 1:**
Baseline: visual diagnosis, single visit in the following order:
 - 1. Visual assessment of tooth surface (method: ICDAS), one time each patient**
 - 2. if applicable: assessment of radiographs, one time each patient**
 - 3. Treatment decision**
 - 4. Bioluminescence measurements (Calcivis imaging system), one time each patient**

Visit 2:

Six months after baseline, same participants: visual diagnosis, single visit in the following order:

- 1. Visual assessment of tooth surface (method: ICDAS), one time each patient**
- 2. if applicable: assessment of radiographs, one time each patient**
- 3. Treatment decision**
- 4. Bioluminescence measurements (Calcivis imaging system), one time each Patient**

Visit 3:

Twelve months after baseline, same participants: visual diagnosis, single visit in the following order:

- 1. Visual assessment of tooth surface (method: ICDAS), one time each patient**
- 2. if applicable: assessment of radiographs, one time each patient**
- 3. Treatment decision**
- 4. Bioluminescence measurements (Calcivis imaging system), one time each patient**



Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **Single arm study**
- Blinding: [---]*
- Who is blinded: [---]*
- Control: **Uncontrolled/Single arm**
- Purpose: **Diagnostic**
- Assignment: **Single (group)**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Primary Outcome: Agreement of visual activity assesement of caries lesions / active lesions in bioluminescence Image

Method: observation. Classification: active lesion caries yes/no

Secondary Outcome

Ability of the bioluminescence method to monitor caries lesions over time.

Method: observation. Classification: 6 and 12 month after baseline examination

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Doctor's Practice **Lollar**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2020/01/22**
- Target Sample Size: **12**

Planned/Actual: **Actual**

(Anticipated or Actual) Date of First Enrollment: **2020/01/22**

Target Sample Size: **12**

- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

- **Signed, written consent before participation in the study**
- **Patients who are willing to attend all study-related appointments**
- **Patients with at least 6 posterior teeth (premolars / molars) without crowns**
- **Patients with at least one occlusal caries on the (premolars / molars)**
- **sound occlusal surfaces and occlusal surfaces with initial and moderate lesions**

Exclusion criteria

- **Patients with hypersensitivity or allergy to proteins (no separate allergy testing planned for the study)**
- **Patients without adequate cooperation during the dental examinations**
- **Patients who do not follow follow-up appointments**
- **pregnant women (no separate pregnancy test planned for the study)**
- **patients with bleached teeth (<2 weeks before measurements)**
- **Patients with acute toothache**
- **Patients with crowns on all premolars and molars**
- **Patients without premolars and molars**
- **Occlusal surfaces with extensive carious lesions (visible dentin caries)**
- **teeth with anomalies, tooth fluorosis or hypomineralisation**

Addresses

- **Primary Sponsor**

Philipps-Universität Marburg, Medizinisches Zentrum für ZMK, Abteilung für Kieferorthopädie
Ms. Prof. Dr. Anahita Jablonski-Momeni
Georg-Voigt Straße 3
35039 Marburg
Germany



Primary Sponsor

Philipps-Universität Marburg, Medizinisches Zentrum für ZMK, Abteilung für Kieferorthopädie

Ms. Prof. Dr. Anahita Jablonski-Momeni

Georg-Voigt Straße 3

35039 Marburg

Germany

Telephone: **06421-5863221**

Fax: [---]*

E-mail: **momeni at staff.uni-marburg.de**

URL: [---]*

■ **Contact for Scientific Queries**

Philipps-Universität Marburg, Medizinisches Zentrum für ZMK, Abteilung für Kieferorthopädie

Ms. Prof. Dr. Anahita Jablonski-Momeni

Georg-Voigt Straße 3

35039 Marburg

Germany

Telephone: **06421-5863221**

Fax: [---]*

E-mail: **momeni at staff.uni-marburg.de**

URL: [---]*

■ **Contact for Public Queries**

Philipps-Universität Marburg, Medizinisches Zentrum für ZMK, Abteilung für Kieferorthopädie

Ms. Prof. Dr. Anahita Jablonski-Momeni

Georg-Voigt Straße 3

35039 Marburg

Germany

Telephone: **06421-5863221**

Fax: [---]*

E-mail: **momeni at staff.uni-marburg.de**

URL: [---]*

Sources of Monetary or Material Support

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

Philipps-Universität Marburg, Medizinisches Zentrum für ZMK, Abteilung für Kieferorthopädie

Ms. Prof. Dr. Anahita Jablonski-Momeni

Georg-Voigt Straße 3

35039 Marburg

Germany



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

Philipps-Universität Marburg, Medizinisches Zentrum für ZMK, Abteilung für Kieferorthopädie

Ms. Prof. Dr. Anahita Jablonski-Momeni

Georg-Voigt Straße 3

35039 Marburg

Germany

Telephone: **06421-5863221**

Fax: [---]*

E-mail: **momeni at staff.uni-marburg.de**

URL: [---]*

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.