Trial Description

Title

Long-term performance and survival rate of press veneered zirconia and monolithic CAD/CAM lithium disilicate crowns: A prospective randomized clinical splitmouth study over 5 years

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

The aim of present clinical study is to evaluate the long-term performance of posterior crowns using two different all-ceramic systems (IPS e.max ZirCAD/ ZirPress SC und IPS e.max CAD Ivoclar- Vivadent, Schaan, Lichtenstein). Each patient will receive two crown restorations, with comparable position of the restorations. Recall evaluation is perfomed over a 5 year period after insertion of the restorations. During the observation period after 1 year, 2, 3 and 5 years restorations are investigated and rated according to standardized clinical parameters.

Brief Summary in Scientific Language

Prosthodonitc restaurations are used to imitate natural teeth in functionand esthetics.The aim of this randomised controlled clinical study is to evaluate the long-term performance of posterior crowns using two different all-ceramic systems (IPS e.max ZirCAD/ ZirPress SC und IPS e.max CAD Ivoclar- Vivadent, Schaan, Lichtenstein). Recall evaluation is perfomed over a 5 year period after insertion of the restorations. A splitmouth design, with comparable position of the restorations is applied in the present clinical study. One of the restorations will be frabricated using IPS e.max ZirCAD/ ZirPress SC ceramics, the other one from IPS e.max CAD. During the observation period (Baseline (2 weeks after insertion), after 1 year, 2, 3 and 5 years all restorations are investigated and rated according to the United States Public Health Service (USPHS) criteria.

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

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Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00000240**
- Date of Registration in DRKS: **2009/10/27**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **no**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **261/09 , Ethik-Kommission der Albert-Ludwigs-Universität Freiburg**

Secondary IDs

- Universal Trial Number (UTN): **U1111-1112-1784**

Health condition or Problem studied

- Free text: **fracture of the restoration, secondary caries**
- ICD10: **K02.9 - Dental caries, unspecified**

Interventions/Observational Groups

- Arm 1: **Long-term performance (probe mirror photos) according to USPHS criteria of crown placement of molar teeth in the controlgroup IPS e.max CAD**
- Arm 2: **Long-term performance (probe mirror photos) according to USPHS criteria of crown placement of molar teeth in the controlgroup IPS e.max CAD**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Active control**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

primary: Survival time of all-ceramic crowns using two all-ceramic systems (taking ointo account technical, biological failures, necessitating a renewal of the restauration)

Secondary Outcome

[---]*

Countries of recruitment

- DE **Germany**

Locations of Recruitment

Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2009/11/15**
- Target Sample Size: **40**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **70 Years**

Additional Inclusion Criteria

Two comparable, teeth (molars) in need of a crown restoration, good oral hygiene, healthy periodontal condition, healthy endodontical condition

Exclusion criteria

Teeth are not in need of a crown restoration

Addresses

■ **Primary Sponsor**

Ivoclar Vivadent AG
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URL: **[---]***

■ **Contact for Scientific Queries**

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Sources of Monetary or Material Support

■ **Commercial (pharmaceutical industry, medical engineering industry, etc.)**

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Status

- Recruitment Status: **Recruiting planned**
- 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.*