PLEASE NOTE: *This trial has been registered retrospectively.*

Trial Description

Title

The clinical success of the permanent posterior filling alternative Equia-additional cohort.

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

Study to compare the higher survival rate of a modified glasionomer system compared towards a conventional Glasionomer in combination with a coating material. A participation of a minimum of three dental clinics is assigned.

Brief Summary in Scientific Language

A prospective clinical trial as cohort study according to MPG phase IV to compare the survival rate of Equia (Fuji IX GP Extra in combination with G-Coat Plus) with Fuji IX (GIC Fuji IX GP fast in combination with Fuji Coat LC) as filling material for posterior teeth.

Organizational Data

- DRKS-ID: **DRKS00005740**
- Date of Registration in DRKS: **2014/03/14**
- 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.: **BB 124/10 , Ethikkommission an der Medizinischen Fakultät der Ernst-Moritz-Arndt-Universität Greifswald**

Secondary IDs

Health condition or Problem studied

- ICD10: **K02 - Dental caries**

Interventions/Observational Groups

- Arm 1: **Filling with a conventional Glasionomer (Fuji IX GP fast + Fuji Coat LC), 40 fillings**
- Arm 2: **Filling with a modified Glasionomer + Coat (EQUIA System, Fuji IX GP Extra in combination with G-Coat Plus), 40 fillings**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **patient/subject, investigator/therapist, assessor**
- Control: **Active control (effective treament of control group)**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Differences in degree of wear and fillings fracture between both products over a five year period according to a calibrated evaluation based on FDI standard (Hickel et al 2010) beginning from Baseline.

Secondary Outcome

Failure rate of all fillings.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Zentrum für Zahn-, Mund- und Kieferheilkunde, Greifswald**
- University Medical Center **Abteilung für Zahnerhaltungskunde LMU München, München**
- University Medical Center **Medizinisches Zentrum für ZMK, Marburg**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2011/04/12**
- Target Sample Size: **240**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

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

Additional Inclusion Criteria

1. Dentate patients (no partial or full dentures, proximately three opposing zones with occlusal contacts of natural teeth in the posterior region), 2. fillings quantity is limited on the multi-surface fillings, 3. the cavity size is limited at 50% of the width of teeth, the proximal walls on the distances of the cusp tip.

Exclusion criteria

1. Patients with CMD dysfunction or malfunction, 2. signs of occlusal abrasion, hyperfunction, clenching will be excluded from the study. CMD-Screening, 3. Patients who withheld their paticipation will be excluded from the study, 4. none one-surface fillings, none completed or partially cusp replacements.

Addresses

- **Primary Sponsor**

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Sources of Monetary or Material Support

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

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Fax: **[---]***
E-mail: **[---]***
URL: **www.gceurope.com**

Status

- Recruitment Status: **Recruiting stopped after recruiting started**
- Study Closing (LPLV): **2015/12/18**

Trial Publications, Results and other documents

- Further trial documents **Weitere Studiendokumente/ further trial 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.*