## Trial Description

### Title

**Effect of Curodont TM Protect on prevention of artificial carious lesions of bovine enamel-an in-situ study**

### Trial Acronym

**Preventive effect of Curodont TM Protect**

### URL of the trial

**[---]***

### Brief Summary in Lay Language

**Initial carious lesions in enamel may progress towards dentine caries with decay without any prevention. While an initial lesion can be arrested with preventive measurements, this is seldom the case in cavitations. The aim of this study is to evaluete whether different measurements are able to arest enamel lesions of further developement. Two different methods serve as test group 1: the established Duraphat varnish, 2: the newly developed Curodont Protect. The human saliva serves as control group. For each participant an individual removable resin appliance is prepared. In each appliance demineralized bovine enamel specimens (sterilized, BSE free) will be inserted. The specimen will be demineralized in a solution in order to simulate initial caries lesions.**

### Brief Summary in Scientific Language

**Initial carious lesions in enamel may progress towards dentine caries with decay without any prevention. While an initial lesion can be arrested with preventive measurements, this is seldom the case in cavitations. The aim of this study is to evaluate whether different measurements are able to arest enamel lesions of further developement. Two different methods serve as test group 1: the established Duraphat varnish, 2: the newly developed Curodont Protect. The human saliva serves as control group without any intervention. For each participant an individual removable resin appliance is prepared. In each appliance demineralized bovine enamel specimens (sterilized, BSE free) will be inserted. The specimen will be demineralized in a solution in order to simulate iinitial caries lesions.**

## Organizational Data

- DRKS-ID: **DRKS00006215**
- Date of Registration in DRKS: **2014/06/04**

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- 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.: **33/14 , Ethik-Kommission des Fachbereichs Medizin der Philipps-Universität Marburg**

## Secondary IDs

## Health condition or Problem studied

- ICD10: **K02.0 - Caries limited to enamel**

## Interventions/Observational Groups

- Arm 1: **Saliva (no intervention, natural saliva in patients´mouth, 4 weeks in total)**
- Arm 2: **Duraphat-Varnish (1x in 4 weeks, 4 weeks in total)**
- Arm 3: **Curodont Protect (2x week, 4 weeks in total)**

## Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Active control (effective treament of control group), Control group receives no treatment**
- Purpose: **Prevention**
- Assignment: **Crossover**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

### Primary Outcome

**Endpoint each arm: 4 weeks after wearing the appliance with specimen.**
**Endpoint of the study: due to the crossover design 12 weeks.**
**Measuring method: loss of mineral in enamel measured by micro-ct and fluoreszence.**

### Secondary Outcome

**Endpoint each arm: 4 weeks after wearing the appliance with specimen.**
**Endpoint of the study: due to the crossover design 12 weeks.**
**Measuring method: surface texture of specimen measured by scanning electron microscopy**

## Countries of recruitment

- DE **Germany**

## Locations of Recruitment

- University Medical Center **Zahnklinik, Marburg**

## Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2014/12/15**
- Target Sample Size: **9**
- 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

**Age ≥ 18 years**
**low caries activity**
**Willing and able to attend the on-study visits and assessments**
**Willing and able to understand all study-related procedures and to follow the self-**

**treatment instructions**
**informed consent**

### Exclusion criteria

**Subjects with removable partial denture;**
**Subjects with fixed orthodontic appliances;**
**Subjects with current dental trauma or surgery;**
**Last applied high-concentration fluoride treatment (elmexgelee, etc.) < 2 weeks;**
**Smoker;**
**Subjects with bronchial asthma;**
**Evidence of tooth erosion;**
**History of head and neck illnesses (e.g. head/neck cancer);**
**Pregnant and breast-feeding women (no pregnancy test will be done for this clinical in situ study. Patient's statement is considered as sufficient.);**
**Any pathology or concomitant medication affecting salivary flow or dry mouth: unstimulated < 0.2 ml/min;**
**Last taking of antibiotics < 2 months**
**Patients receiving medication known to stain teeth like tetracycline or chlorhexidine**
**high caries risk;**
**Concurrent participation in another clinical trial;**
**Subjects with known allergies//hypersensitivity towards agent of Curodont Protect or Duraphat varnish respectively.**

## Addresses

■ **Primary Sponsor**

**Medizinisches Zentrum für ZaMK, Abteilung für Kinderzahnheilkunde**
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■ **Collaborator, Other Address**

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## Sources of Monetary or Material Support

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

**Medizinisches Zentrum für ZMK, Abteilung für Kinderzahnheilkunde**
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- **Private sponsorship (foundations, study societies, etc.)**

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## Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2015/07/15**

## Trial Publications, Results and other documents

- Paper **Publication**

** 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.*