



## Trial Description

### Title

**Dental fear in early childhood caries and the caries risk in the permanent dentition - an analytic-epidemiological study**

### Trial Acronym

**ECC dental fear study - follow-up**

### URL of the trial

[---]\*

### Brief Summary in Lay Language

**Despite success in dental caries prevention in adolescents, caries prevention in the early primary dentition in some risk groups is less effective. An analytic-epidemiologic study focussed on caries risk factors was designed to evaluate the caries risk in the primary dentition of those patients after 15 yrs. Additionally, risk factors are to be proved to determine its long-term prediction**

### Brief Summary in Scientific Language

**This is an longitudinal observational study in juvenile patients that were dentally treated under general anaesthesia as a child due to dental anxiety. Primary endpoint is the caries lifetime experience, secondary endpoint is dental anxiety. As a control group, a cohort of juveniles of the same age will serve that were treated ambulantly during the same time period. The evaluation of the endpoint takes place about 15 yrs after the dental treatment**

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

[---]\*

### Description IPD sharing plan

[---]\*

## Organizational Data

- DRKS-ID: **DRKS00000516**
- Date of Registration in DRKS: **2011/02/07**
- 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**



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Investigator Sponsored/Initiated Trial (IST/IIT): **yes**

Ethics Approval/Approval of the Ethics Committee: **Approved**

- (leading) Ethics Committee Nr.: **39/2010 , Ethik-Kommission der Universität Witten/Herdecke**

## Secondary IDs

- Universal Trial Number (UTN): **U1111-1111-4056**

## Health condition or Problem studied

- ICD10: **K02.0 - Caries limited to enamel**
- Free text: **dental anxiety**
- ICD10: **K02.1 - Caries of dentine**
- ICD10: **K02.2 - Caries of cementum**
- ICD10: **K02.3 - Arrested dental caries**
- ICD10: **K02.8 - Other dental caries**
- ICD10: **K02.9 - Dental caries, unspecified**

## Interventions/Observational Groups

- Arm 1: **test group: children were treated under general anaesthesia due to dental anxiety**
- Arm 2: **control group: ambulant dental treatment of children**

## Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Epidemiological study**
- Allocation: **Non-randomized controlled trial**
- Blinding: **Open (masking not used)**
- Who is blinded: [---]\*
- Control: **Active control**



Study Type: **Non-interventional**

Study Type Non-Interventional: **Epidemiological study**

Allocation: **Non-randomized controlled trial**

Blinding: **Open (masking not used)**

Who is blinded: [---]\*

Control: **Active control**

- Purpose: **Prevention**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): [---]\*

### Primary Outcome

**caries lifetime experience (DMF index) ca. 15 yrs after treatment**

### Secondary Outcome

**Questionnaire for recording individual dental anxiety according to the HAF scale (Jöhren; 1999)**

**ca. 15 yrs after treatment**

### Countries of recruitment

- **DE Germany**

### Locations of Recruitment

### Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2011/09/20**
- Target Sample Size: **250**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**



### **Inclusion Criteria**

- Gender: **Both, male and female**
- Minimum Age: **16 Years**
- Maximum Age: **27 Years**

### **Additional Inclusion Criteria**

- **date of birth 1983-1994**
- **treated at University Witten/ Herdecke at the age of 3-5 years.**

### **Exclusion criteria**

- **no dental treatment at the University of Witten/ Herdecke in the Year 1995**
- **no given .....**

### **Addresses**

#### ■ **Primary Sponsor**

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#### ■ **Secondary Sponsor**

Telephone: **[---]\***

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#### ■ **Contact for Scientific Queries**

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**Department ZMK**

**Abteilung für Zahnärztliche Propädeutik**

**Mr. Dr.med.dent; M.Sc. A. Rainer Jordan**

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## Sources of Monetary or Material Support

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

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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.*