

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

## Trial Description

### Title

**Evaluation of a dental preventive program for 0- to 3 year old Thuringian children, Germany**

### Trial Acronym

[---]\*

### URL of the trial

[---]\*

### Brief Summary in Lay Language

**Early Childhood Caries (ECC) is most common chronic disease in childhood and affects children`s growth. In cooperation of the Department of Preventive and Paediatric Dentistry (DPPD) and Youth Welfare Office (YWO) of Jena, Thuringia, a preventive program was initiated in 2009.**

**Purpose of this intersectoral program was the implementation of evidence based preventive and intervention strategies for early ECC onset.**

**Trained staff of YWO visited all parents of newborns. Parents were advised about oral hygiene including practical tooth brush training, diet, use of fluorides, infectious etiology of ECC and the importance of the first dental visit after tooth eruption. In the first year of live the children were invited by YWO to dental examination and counselling in the DPPD. Children were included in a risk related recall system (quarterly to semiannually). Aim of this study was the investigation of the impact of the program on oral health of the children after 3 and 5 years. The hypothesis is that with early dental visits and a closed intersectoral cooperation ECC is preventable. For a comprehensive programme evaluation the programme was continued to the age of 5 years.**

### Brief Summary in Scientific Language

#### Background

**Early Childhood Caries (ECC) is most common infectious disease in childhood and affects children`s growth. In cooperation of the Department of Preventive and Paediatric Dentistry (DPPD) and Youth Welfare Office (YWO) of Jena, Thuringia, a preventive program was initiated in 2009.**

#### Aim

**Purpose of this intersectoral program was the implementation of evidence based preventive and intervention strategies for early ECC onset and the investigation of the impact on oral health of 0-to 3-year old children.**

#### Design

**Trained staff of YWO visited all parents of newborns. From 7/2009 to 7/2010 1162 newborns were born and visited by the YWO. Parents were advised about oral hygiene including practical tooth brush training, diet, use of fluorides, infectious**



**etiology of ECC and the importance of the first dental visit after tooth eruption. Parents had the opportunity to take part in the preventive program and received a patient information and consent form. In the first year of live the children were invited by YWO to dental examination and counselling in the DPPD. 512 (44.1%) children were in the intervention group and included in a risk related recall system (quarterly or semiannually). For preventing initial caries progression lesions were treated by fluoride varnish application (Fluoridin N5, VOCO GmbH, Germany). Children for the control group didn't take part in the preventive program and were invited by YWO to attend a dental examination in the DPPD after 3 and 5 years for a program evaluation.**

## Organizational Data

- DRKS-ID: **DRKS00003438**
- Date of Registration in DRKS: **2012/02/22**
- 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.: **2759-02/10 , Ethikkommission der Friedrich-Schiller-Universität Jena an der Medizinischen Fakultät**

## Secondary IDs

## Health condition or Problem studied

- ICD10: **K02 - Dental caries**

## Interventions/Observational Groups

- Arm 1: **Intervention group received counselling by YWO and take part in the preventive program: first dental visit in first year of life and participation in a risk-related recall system with semiannually or quarterly dental check ups. Initial caries lesions were treated by fluoride varnish application. Evaluation of the program at age 6. Recording of plaque, dmfs/dmft, migration background, socio-economic status**
- Arm 2: **Control group: no participation in preventive program, comparison after 3 years duration**

## Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: [---]\*



Study Type: **Interventional**

Study Type Non-Interventional: [---]\*

- Allocation: **Non-randomized controlled trial**
- Blinding: [---]\*
- Who is blinded: [---]\*
- Control: **Control group receives no treatment**
- Purpose: **Prevention**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

### Primary Outcome

**Scoring by using WHO diagnostic criteria at dmfs/dmft level without radiography. Recording of initial caries lesions, plaque, caries risk, migration background, number of dental appointments, fluoride varnish application, questionnaire about socio-economic status, oral hygiene and diet after 3 and 5 years duration of the preventive program**

### Secondary Outcome

**Statistical analysis using SPSS, logistic regression analysis, ANOVA and chi-square test, p-value of <0.05**

### Countries of recruitment

- DE **Germany**

### Locations of Recruitment

- other **Erstbesuchsdienst der Stadt Jena (Jugendamt), Jena**

### Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2010/02/27**
- Target Sample Size: **800**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

### Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **0 Months**
- Maximum Age: **6 Years**

### Additional Inclusion Criteria

**Recruitment of the intervention group after birth, counseling by Youth Welfare Office, participation in preventive program, first dental visit in first year of life, risk related recall system with semiannually or quarterly examinations for 6 years**

### Exclusion criteria

**No participation in preventive program, nonappearance to dental examinations**

### Addresses

#### ■ Primary Sponsor

**Universitätsklinikum Jena  
Zentrum für Zahn-, Mund- und Kieferheilkunde  
Poliklinik für Präventive Zahnheilkunde und Kinderzahnheilkunde  
Ms. Dr. Yvonne Wagner  
Bachstr. 18  
07740 Jena  
Germany**

Telephone: **03641/934801**

Fax: **03641/93802**

E-mail: **wagner-yvonne at gmx.de**

URL: **<http://www.kiza.uniklinikum-jena.de/Home.html>**

#### ■ Contact for Scientific Queries

**Universitätsklinikum Jena  
ZZMK  
Poliklinik für Präventive Zahnheilkunde und Kinderzahnheilkunde  
Ms. Dr. Yvonne Wagner  
Bachstr. 18  
07740 Jena  
Germany**

Telephone: **03641/934801**

Fax: **03641/934802**

E-mail: **wagner-yvonne at gmx.de**

URL: **<http://www.kiza.uniklinikum-jena.de/Home.html>**

#### ■ Contact for Public Queries



### Contact for Public Queries

**Universitätsklinikum Jena  
ZZMK  
Poliklinik für Präventive Zahnheilkunde und Kinderzahnheilkunde  
Ms. Dr. Yvonne Wagner  
Bachstr. 18  
07740 Jena  
Germany**

Telephone: **03641/934801**

Fax: **03641/934802**

E-mail: **wagner-yvonne at gmx.de**

URL: **<http://www.kiza.uniklinikum-jena.de/Home.html>**

### Sources of Monetary or Material Support

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

**Universitätsklinikum Jena, ZZMK, Poliklinik für Präventive Zahnheilkunde und  
Kinderzahnheilkunde  
Ms. Dr. Yvonne Wagner  
Bachstr. 18  
07740 Jena  
Germany**

Telephone: **03641/934801**

Fax: **03641/934802**

E-mail: **wagner-yvonne at gmx.de**

URL: **<http://www.kiza.uniklinikum-jena.de/Home.html>**

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

**BaMed AG  
Sihleggstrasse 15  
8832 Wollerau  
Switzerland**

Telephone: [---]\*

Fax: [---]\*

E-mail: [---]\*

URL: [---]\*

■ **Public funding institutions financed by tax money/Government funding body  
(German Research Foundation (DFG), Federal Ministry of Education and  
Research (BMBF), etc.)**

**DGZMK  
Deutsche Gesellschaft für Zahn-, Mund- und Kieferheilkunde  
Liesegangstr. 17 a  
40211 Düsseldorf**

---

**Public funding institutions financed by tax money/Government funding body  
(German Research Foundation (DFG), Federal Ministry of Education and  
Research (BMBF), etc.)**

**DGZMK  
Deutsche Gesellschaft für Zahn-, Mund- und Kieferheilkunde  
Liesegangstr. 17 a  
40211 Düsseldorf  
Germany**

Telephone: [---]\*

Fax: [---]\*

E-mail: [---]\*

URL: [---]\*

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

**VOCO GmbH  
P.O.B./Postfach 767  
27457 Cuxhaven  
Germany**

Telephone: [---]\*

Fax: [---]\*

E-mail: [---]\*

URL: [---]\*

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

**Procter & Gamble International Operations S.A.  
47, Rte de St. Georges  
1213 Petit-Lancy  
Switzerland**

Telephone: [---]\*

Fax: [---]\*

E-mail: [---]\*

URL: [---]\*

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

**Wrigley GmbH  
Biberger Str. 18  
82008 Unterhaching  
Germany**

Telephone: [---]\*

Fax: [---]\*

E-mail: [---]\*

URL: [---]\*

DRKS-ID: **DRKS00003438**

Date of Registration in DRKS: **2012/02/22**

Date of Registration in Partner Registry or other Primary Registry: [---]\*

## Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2014/11/04**

## Trial Publications, Results and other documents

- Paper **Evaluation of an interdisciplinary preventive programme for early childhood caries: findings of a regional German birth cohort study. DOI: 10.1007/s00784-015-1685-z. CLOI-D-15-00066.1**

\* *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.*