

Trial Description

Title

Maintenance of oral health in preterm children by preventive oral care

Trial Acronym

Preterm Children Study Long

URL of the trial

[---]*

Brief Summary in Lay Language

In 2011 9% of all births in Germany were preterm, which is one of the highest rates of preterm birth in Europe. Preterm birth can affect multiple internal organs and organ-systems. Regarding oral structures, in preterm children oral health problems such as tooth developmental problems, tooth eruption disorders and jaw abnormalities are often observed. One of the most common complications are defects of the tooth structure in form of enamel hypoplasia in the deciduous and permanent dentition, which are associated with a higher risk of caries. The present study is observing, if oral health of preterm children will enhance by intensive caries-preventive measures in comparison with basic caries-preventive measures. Therefore, patients are split into two groups. One group receives basic caries-prevention program and the other group intensive caries-prevention program. In addition, the relationship between the nutritional status of preterm children and their tooth development is analysed. As a result of this study, evidence based recommendations for preventive measures in order to maintain oral health in preterm children are deduced.

Brief Summary in Scientific Language

The aims of this prospective interventional case-control study with a randomized patient selection are 1. to compare oral health status of preterm children after basic prevention program and after intensified prevention program. 2. to analyse the relationship between nutrition status and tooth development in preterm children. 3. to develop evidence based preventive and therapeutic recommendations for this specific group of patients.

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

[---]*

Description IPD sharing plan

[---]*



Organizational Data

- DRKS-ID: **DRKS00006841**
- Date of Registration in DRKS: **2015/04/09**
- 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.: **4111-06/14 , Ethikkommission der Friedrich-Schiller-Universität Jena an der Medizinischen Fakultät**

Secondary IDs

- Universal Trial Number (UTN): **U1111-1162-5414**

Health condition or Problem studied

- ICD10: **K02 - Dental caries**
- ICD10: **K00 - Disorders of tooth development and eruption**

Interventions/Observational Groups

- Arm 1: **Intervention Group: oral examination, oral hygiene status, professional tooth cleaning.Topical Fluoridation (22.500 ppm Fluoride) quarterly starting after eruption of the first tooth**
- Arm 2: **Kontrol Group: oral examination, oral hygiene status, professional tooth cleaning and topical Fluoridation (22.500 ppm Fluoride) half yearly**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: [---]*
- Allocation: **Randomized controlled trial**
- Blinding: [---]*
- Who is blinded: [---]*
- Control: **Active control**
- Purpose: **Prevention**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **No**

Primary Outcome

Caries experience measured with the Decayed - Missing - Filled - Teeth Index in the primary and permanent dentition (dmft/DMFT) every year

Secondary Outcome

Defects of tooth structures measured by Developmental Defects of Enamel Index in the Primary and permanent dentition (DDE) yearly

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **University Hospital - Dental Clinic, Jena**

Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2015/05/04**
- Target Sample Size: **200**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **6 Months**
- Maximum Age: **12 Years**

Additional Inclusion Criteria

preterm birth

Exclusion criteria

term birth



Addresses

■ Primary Sponsor

Universitätsklinikum JenaZZMK Poliklinik für Präventive Zahnheilkunde und Kinderzahnheilkunde
Ms. Prof. Dr. Roswitha Heinrich-Weltzien
Bachstr. 18
07740 Jena
Germany

Telephone: **00493641934801**

Fax: **00493641934802**

E-mail: **Roswitha.Heinrich-Weltzien at med.uni-jena.de**

URL: **www.kiza.uniklinikum-jena.de**

■ Contact for Scientific Queries

Jena University HospitalZZMK - Poliklinik für Präventive Zahnheilkunde und Kinderzahnheilkunde
Ms. Dr. Ina M. Schüler
Bachstraße 18
07743 Jena
Germany

Telephone: **03641 934803**

Fax: **03641 934802**

E-mail: **Ina.Schueler at med.uni-jena.de**

URL: [---]*

■ Contact for Public Queries

Jena University HospitalZZMK - Poliklinik für Präventive Zahnheilkunde und Kinderzahnheilkunde
Ms. Dr. Ina M. Schüler
Bachstraße 18
07743 Jena
Germany

Telephone: **03641 934803**

Fax: **03641 934802**

E-mail: **Ina.Schueler at med.uni-jena.de**

URL: [---]*

Sources of Monetary or Material Support

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

Universitätsklinikum Jena

DRKS-ID: **DRKS00006841**

Date of Registration in DRKS: **2015/04/09**

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



Deutsches Register
Klinischer Studien

German Clinical
Trials Register

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

Universitätsklinikum Jena

Bachstraße 18

07740 Jena

Germany

Telephone: [---]*

Fax: [---]*

E-mail: [---]*

URL: **www.uniklinikum-jena.de**

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.