Trial Description

Title

The impact of molar-incisor hypomineralization (MIH) on the child’s oral health-related quality of life in children before and after dental management

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

Brief description
For some time now, the quality of life of the children is investigated with regard to their oral health. In representative cross-section studies, a population of all children was questioned. Children who undergo orthodontic therapy and wear braces were also interview to determine possible deviations.

Molar Incisor hypomineralization, commonly known as MIH, is a frequent mineralization disorder of the permanent teeth, the impact of which has not yet been investigated on the oral health related quality of life of the affected children. Since the teeth have large structural defects and undergo post eruptive breakdown of the enamel, the quality of life can be restricted. The aim of this studies is to determine the impact of molar-incisor hypomineralization on the oral health-related quality of life in children aged 7-14 years before and after dental management by using the German 19-item version of the Child Oral Health Impact Profile (COHIP-G19). If the presumed hypothesis was confirmed, we would like to point out individualized and adapted dental management strategies in the future. The classical treatment of Molar Incisor hypomineralization is followed by the guidelines of the European Society for Pediatric Dentistry (EAPD). However, these guidelines do not address the factor of quality of life. Therefore, the aim of this study is to develop therapeutic guidelines that are tailored to the individual quality of life of patients.

Brief Summary in Scientific Language

Mottled enamel, non-endemic mottling of enamel, internal enamel hypoplasia, cheese molars, non-fluoride enamel opacities, opaque spots and idiopathic enamel opacities are all different terms used to describe the condition currently known as molar-incisor hypomineralization (MIH). Weerheijm first introduced the terminology of MIH in 2001, describing demarcated, qualitative developmental enamel defects of one or more of the permanent molars. The clinical characteristics can vary, both, between different patients as well as on tooth level in the same patient; however, no gender-related distribution differences have been reported. The prevalence of such defects is common in Europe and ranges from 3.6% to 21.8%. Dental management of MIH resembles a challenge for pediatric dentists, due to the variation in clinical appearance and the broad spectrum of treatment modalities, which range from prevention, restorations to
There are EAPD-guidelines how to treat MIH but without a relation to the oral-health related quality of life. It was reported that the dental management need of affected children is much higher than in non-affected ones. In severe MIH cases, a post-eruptive enamel breakdown (PEB) in the affected permanent molars is to be expected, because of the sub-surface porous structure and the detrimental effect of masticatory forces in this area. The post-eruptive breakdown of enamel encourages caries progression leading to pulpal involvement and causes different degrees of hypersensitivity that range from occasional hypersensitivity as a result of external mechanical or thermal stimuli to persistent/spontaneous hypersensitivity. In addition, to the hypersensitivity an esthetic burden is obvious, in case of permanent incisors involvement, all of which may negatively affect the child’s general health, quality of life and socio-psychological status. Oral health-related quality of life (OHRQoL) is a multidimensional instrument used to describe the patient’s self-perceived impact of oral health problems and evaluates the treatment significance from the patients’ perspective. Increased attention has lately been paid to the assessment of the oral health-related quality of life as an important part of the overall general health.

The influence of some dental conditions such as dental caries, malocclusion and tooth erosion on the disturbance of a child’s daily activities have been addressed in the literature. Studying the OHRQoL has proved to play an important role in planning public health policies and assessing different dental management modalities. The last decade has witnessed a great amount of research regarding the prevalence, diagnosis, management and etiology of MIH; however, no study addressed the impact of this condition on the children’s OHRQoL. Thus, the aim of this study is to assess the influence of different grades of molar-incisor hypomineralization on the OHRQoL before and after dental treatment.

Aim
Determine the impact of molar-incisor hypomineralization on the oral health-related quality of life in children aged 7-14 years before and after dental management by using the German 19-item version of the Child Oral Health Impact Profile (COHIP-G19).

Child Oral Health Impact Profile (COHIP-G19)
The original COHIP is a 34-item questionnaire that has been established to measure the OHRQoL in children and adolescents at the age of 8 to 15 years. The questionnaire is divided into 5 subscales (oral health, school environment, self-image, emotional well-being and functional well-being). It is the first OHRQoL measurement tool for children to include, both, the positive and negative health impacts. Recently a 19-item short version of COHIP has been introduced by Broder et al., which was then translated and validated by Sierwald et al., giving rise to the German 19-item short version (COHIP-G19). The COHIP-G19 consists of 3 subscales, however, the 19 items have been extracted from each of the 5 subscales of the original 34-item COHIP long version: Oral health well-being (5 items), functional well-being (4 items), emotional well-being (6 items), school environment (2 items) and self-image (2 items), whereas in the short version the last three subscales have been merged together in one called social/emotional, school and self-image subscale and consisting of 10 items. The participants are to report their experience with the positive or negative impact in the last 3 months on a scale of 0 to 4.0 = never, 1 = almost never, 2 = sometimes, 3 = fairly often and 4 = almost all the time. COHIP-G19 summary scores range from 0 (worst OHRQoL) to 76 (best OHRQoL). The short COHIP version is advantageous in many ways; it is quicker and easier to be administered, which is more convenient for the respondents. Moreover, it covers a wider age range (7-17 years) in comparison to the age range validated using the long form (8-15 years).
Dependent variables
Children’s oral health-related quality of life before and after treatment of MIH.

Independent variables
• Number of affected and not treated teeth (surfaces)
• Severity of MIH (according to the EAPD criteria)
• Presence of caries in affected teeth (surface)
• Presence of hypersensitivity
• Involvement of the permanent incisors
• Dental treatment (intervention)

Materials and Methods
• Study design
Cross-sectional study with a multi-center, multi-stage random sample
• Sample size (CI 95%, Power 80%): N = 100 patients with mild, 100 patients with severe and 100 patients without MIH (control group) (Fig. 1)
** The control group will consist of symptomless patients that meet the inclusion criteria age group and will answer the COHIP G19 questionnaire.
• Consent form of the caregivers
• Calibration of the examiners (inter- and intra-examiner agreement)
• Recruitment of participants

• MIH diagnosis will be performed according to the EAPD criteria

Demarcated opacity
Post-eruptive enamel breakdown (PEB)
A demarcated defect involving an alteration in the translucency of the enamel, variable in degree. The defective enamel is of normal thickness with a smooth surface and can be white, yellow or brown in color.
A defect that indicates a deficiency of the surface after the eruption of the tooth. Loss of initially formed surface enamel after tooth eruption. The loss is often associated with a pre-existing demarcated opacity.

• The last three criteria “atypical restoration”, “extracted molar due to MIH” and “Unerupted” cannot be used in this study, since they lead to the exclusion of the participant

• The participant will be graded as having mild or severe MIH according to the most affected tooth/surface recorded
• Severity grading
Mild
There are demarcated enamel opacities without enamel breakdown, occasional sensitivity to external stimuli e.g. air/ water but not brushing and only mild esthetic concerns about the discoloration of the incisors.
Severe
There are demarcated enamel opacities with enamel breakdown, caries, persistent/ spontaneous hypersensitivity affecting function e.g. during brushing and finally strong esthetic concerns that may have socio-psychological impact.
• Assessment of the degree of hypersensitivity using a visual analogue scale and the Schiff score
• Each participant will answer the German 19-item version of the Child Oral Health Impact Profile (COHIP-G19)
  • All applied questionnaires will be paper-based and self-administered by the participants
  • Data collection on tooth surface level will be collected using the standardized clinical recording data sheet
  • Visual Analog Scale (VAS) and the Schiff Cold Air Sensitivity Scale (SCASS) will be used to determine the pain intensity
  • Findings will be noted in the case report file
  • All the data will be collected and saved in form of a SPSS table
  • Statistical data analysis (SPSS)

Statistics
• Descriptive statistics
• Kappa statistics for reliability (inter and intra-examiner agreement)
• Linear regression analysis

Organizational Data

- DRKS-ID: DRKS00011882
- Date of Registration in DRKS: 2017/03/21
- 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.: EA2/104/16, Ethik-Kommission der Charité - Universitätsmedizin Berlin-

Secondary IDs

ICD10: K00.4 - Disturbances in tooth formation

Health condition or Problem studied

Interventions/Observational Groups

- Arm 1: Patients with severe MIH (molar incisive hypomineralization) will be questioned twice, once before and once, 2 weeks after dental Treatment, regarding their Quality of life with the COHIP "Shortform G-19" questionnaire.
- Arm 2: Patients with mild MIH (molar incisive hypomineralization) will be questioned twice, once before and once, 2 weeks after dental Treatment, regarding their Quality of life with the COHIP "Shortform G-19" questionnaire.
- Arm 3: Patients without MIH (control group) will be questioned once, regarding their quality of life with the questionnaire COHIP "Shortform G-19".
### Characteristics

- **Study Type:** Non-interventional
- **Study Type Non-Interventional:** Observational study
- **Allocation:** Non-randomized controlled trial
- **Blinding:** [---]*
- **Who is blinded:** [---]*
- **Control:** Other
- **Purpose:** Other
- **Assignment:** Parallel
- **Phase:** N/A
- **Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels):** N/A

### Primary Outcome

The aim of this study is to determine the impact of molar-incisor hypomineralization on the oral health-related quality of life in children aged 7-14 years before and after dental management by using the German 19-item version of the Child Oral Health Impact Profile (COHIP-G19).

### Secondary Outcome

/  

### Countries of recruitment

- DE Germany

### Locations of Recruitment

- University Medical Center Charité - Universitätsmedizin Berlin, Centrum für Zahn-, Mund- und Kieferheilkunde, Berlin
- Doctor's Practice Beckum

### Recruitment

- Planned/Actual: Actual
- (Anticipated or Actual) Date of First Enrollment: 2017/05/01
- Target Sample Size: 300
- Monocenter/Multicenter trial: Multicenter trial
**Inclusion Criteria**

- Gender: **Both, male and female**
- Minimum Age: **7 Years**
- Maximum Age: **14 Years**

**Additional Inclusion Criteria**

Age 7 to 14 years, light and severe MIH on at least one untreated, remaining molar (MIH group) or oral health (control group), no pretreatment of the tooth by dentist (fissure seal, filling, crown, extraction) more than one third of the tooth crown being visible.

**Exclusion criteria**

Age: Less than 7 years and older than 14 years, no MIH on a permanent molar (MIH group) or child has dental diseases (control group), Eruption of less than one third of the clinical crown of the tooth, MIH tooth has already been treated by dentist mental retardation, Lasting use of pain medication

**Addresses**

- **Primary Sponsor**

  Charité - Universitätsmedizin Berlin CC 03, CharitéCentrum für Zahn-, Mund- und Kieferheilkunde / CBFAbt. für Kieferorthopädie, Orthodontie und Kinderzahnmedizin
  Äßmannshauuser Str. 4-6
  14197 Berlin
  Germany

  Telephone: [--]*
  Fax: [--]*
  E-mail: [--]*
  URL: www.charite.de

- **Contact for Scientific Queries**
Contact for Scientific Queries

Charité - Universitätsmedizin Berlin Abteilung für Kieferorthopädie, Orthodontie und Kinderzahnmedizin
Mr. Dr. Paul-Georg Jost-Brinkmann
Aßmannshauer Str. 4-6
14197 Berlin
Germany

Telephone: +49 30 450-562521
Fax: +49 30 450-562952
E-mail: paul-g.jost-brinkmann at charite.de
URL: [---]*

Contact for Public Queries

Charité - Universitätsmedizin Berlin CC 03, Charité Centrum für Zahn-, Mund- und Kieferheilkunde / CBFAbt. für Kieferorthopädie, Orthodontie und Kinderzahnmedizin
Mr. Karim Elhennawy
Aßmannshauer Str. 4-6, 14197 Berlin
14197 Berlin
Germany

Telephone: +4930450 562 594
Fax: +4930450 562 952
E-mail: karim.elhennawy at charite.de
URL: [---]*

Sources of Monetary or Material Support

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

Charité Campus Benjamin Franklin
Hindenburgdamm 30
12203 Berlin
Germany

Telephone: [---]*
Fax: [---]*
E-mail: [---]*
URL: www.charite.de

Status

Recruitment Status: Recruiting ongoing
Study Closing (LPLV): [---]*
Trial Publications, Results and other documents

- Approval of ethics comm. (mandatory for transfer to Studybox) Ethical approval

* 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.