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

Trial Description

Title

**Efficacy of two different dentinal hypersensitivity reducing mouth rinses in patients with pain caused by professional tooth cleaning
-single-blind, randomized, controlled, clinical study-**

Trial Acronym

pain control during PTC

URL of the trial

[---]*

Brief Summary in Lay Language

To improve patient comfort, we would like to reduce the pain occurring within the professional dental cleaning. The pain in the purification have following character: usually short, pointed. Therefore, the approach to use a mouthwash against sensitive teeth before cleaning to reduce the resulting pain. The active ingredients work so that they close the dentinal tubules. Two of these preparations are compared in the present study, each against a placebo. The study hypothesis is that the placebo product probably has no proves contrary to the agents of the other two products. Which product is better cuts show the study.

Brief Summary in Scientific Language

The regular use of mouthwashes against sensitive teeth should affect the pain and sensitivities during professional tooth cleaning (PTC). The effect is measured using VAS and VRS. The aim is to increase patient comfort in PTC

Organizational Data

- DRKS-ID: **DRKS00010811**
- Date of Registration in DRKS: **2017/06/27**
- 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.: **16-257 , Ethik-Kommission der Medizinischen Fakultät der Universität zu Köln**

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Secondary IDs

Health condition or Problem studied

- ICD10: **K08 - Other disorders of teeth and supporting structures**
- Free text: **Dentin Hypersensitivity**
- ICD10: **K03.8 - Other specified diseases of hard tissues of teeth**

Interventions/Observational Groups

- Arm 1: **Listerine sensitive professional mouthwash, 7 d before the professional teeth cleaning, 20ml/d 2x/d**
- Arm 2: **Elmex sensitive professional mouthwash, 7 d before the professional teeth cleaning, 20ml/d 2x/d**
- Arm 3: **Alverde 5 in 1 Nanaminze mouthwash, 7 d before the professional teeth cleaning, 20ml/d 2x/d**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **investigator/therapist**
- Control: **Placebo, Active control (effective treament of control group)**
- Purpose: **Prevention**
- Assignment: **Parallel**
-

Study Type: **Interventional**

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Allocation: **Randomized controlled trial**

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Who is blinded: **investigator/therapist**

Control: **Placebo, Active control (effective treament of control group)**

Purpose: **Prevention**

Assignment: **Parallel**

Phase: **N/A**

- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

The pain during the professional cleaning of the teeth is measured by means of a questionnaire according to the PZR, which is measured via Visual Analog Scale (in mm) and Visual Reading Scale (in words)

Secondary Outcome

Quality of life and adherence to the product, as well as general information about the products used, will be determined by questionnaires. Safety will be documented by oral examination

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Zahnklinik, Abteilung der Zahnerhaltung und Parodontologie, Köln**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2017/02/01**
- Target Sample Size: **210**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

To be eligible, a patient must comply with all of the following criteria:
1)Age range: at least 18 years (>1996)
2)Written informed consent
3)periodontal maintenance or dental prophylaxis patient
4)Recall frequency twice a year (or more)
5)Recall appointment third or more

Exclusion criteria

• requiring treatment carious lesions
• antibiotic therapy (up to 7 days prior to study entry)
• Long time medicamentation with analgesics or anti-inflammatory drugs
• Allergies against mouthwashes or their ingredients used
• Pregnant and lactating women
• Expected unavailability for the period of study

Addresses

- **Primary Sponsor**

  Abteilung der Zahnerhaltung und Parodontologie der Zahnklinik Uni Köln
  Kerpener Strasse 32
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  Fax: **[---]***
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Sources of Monetary or Material Support

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

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Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

Status

- Recruitment Status: **Recruiting ongoing**
- 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.*