Trial Description

Title

Patients burdens in prosthodontic treatment by undergraduate students at a Dental School: an evaluation within clinical course and comparison towards standard values of the BiPD-Questionaire.

Trial Acronym

PPP-Study-2

URL of the trial

[---]*

Brief Summary in Lay Language

There are no information from surveys about patients experience and coping with dental procedures performed by undergraduate students in a Dental School setting. Such surveys would not only give a hint about how patients feel under such treatment. It would also enable the Dental School to optimize patient education, information and students education. Due to budget cuts in Dental Education, it is import for clinical teaching, that educational efforts are focussed to the relevant aspects. Such aspects are treatments, which are experienced as burdens and inconveniences by patients. Furthermore it is known, that inconviniences during treatment effects the later outcome with the prosthetic denture.

Brief Summary in Scientific Language

The "Burdens in Prosthetic Dentistry Questionair" (BiPD-Q) copes with burdens during prosthodontic treatment. Generally, quality of treatments can be subdiveded in result-related, structurewise, and process-related aspects. For prosthodontic treatments no process-related studies are available. This, the BiPD-Q was established and validated with 104 patients in 2013 by Reissmann et.al. The questionaire contains burdens with: patient information, local anesthesia, tooth preparation, impression taking, treatment with provisionals, try-in of frameworks, luting of restorations and other conservative measures such as fillings and periodontal therapy.
The questionaire was estabilished in private practice setting mainly with fixed dental prostheses (86.5%) and is based on visual analog scales of 10cm (VAS) for answering.
As this is a handy option for continuous survey in a dental school setting, the objective of the questionaire campaign is to evaluate patients experience in the Dental School setting and to compare it to standard values from the validation cohort in private practice.

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

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Description IPD sharing plan

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Organizational Data

- DRKS-ID: **DRKS00008029**
- Date of Registration in DRKS: **2015/04/21**
- 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.: **226/2015BO2 , Ethik-Kommission an der Medizinischen Fakultät der Eberhard-Karls-Universität und am Universitätsklinikum Tübingen**

Secondary IDs

Health condition or Problem studied

- ICD10: **K08.1 - Loss of teeth due to accident, extraction or local periodontal disease**
- ICD10: **K03.9 - Disease of hard tissues of teeth, unspecified**

Interventions/Observational Groups

- Arm 1: **BiPD-Questionaire for all patients under treatment within the undergraduate courses in prosthodontics at the Tuebingen University Dental School**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **Single arm study**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Uncontrolled/Single arm**
- Purpose: **Treatment**
- Assignment: **Single (group)**

Study Type: **Non-interventional**

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

Allocation: **Single arm study**

Blinding: **[---]***

Who is blinded: **[---]***

Control: **Uncontrolled/Single arm**

Purpose: **Treatment**

Assignment: **Single (group)**

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

Primary Outcome

Comparison of BiPD-Q Values evaluated during undergraduate treatment with norm values of the validation study for the BiPD-Questionaire for each therapy mile stone and after treatment completion.

Secondary Outcome

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Tübingen**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2015/04/22**
- Target Sample Size: **60**
- 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

Treatment within the undergraduate clinical course for prosthodontics

Exclusion criteria

none; not willing to participate in survey

Addresses

- **Primary Sponsor**

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- **Contact for Scientific Queries**

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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 complete, follow-up complete**
- Study Closing (LPLV): **2015/08/21**

Trial Publications, Results and other documents

- Further trial documents **Patienteninformation zur Teilnahme**

** 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.*