ISRCTN99907946 https://doi.org/10.1186/ISRCTN99907946

OHIP study in edentulous population

Submission date
23/01/2018

Recruitment status
No longer recruiting

Registration date
02/02/2018

Overall study status
Completed

Last Edited
23/01/2023

Condition category
Oral Health

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
People who have lost teeth (edentulous) can be treated with false teeth (dentures). The process of making dentures is relatively quick and can take around one or two weeks. Patients also have to go through a process of adaptation to the dentures. During this period of adaptation, certain corrections need to be made. The corrections could be related to the base of the denture, to the artificial teeth in the dentures, or both. This study aims to recruit and observe about denture wearers to look at the improvement in their treatment and satisfaction with their dentures after adequate corrections.

Who could participate?
Patients over 60 years of age who require complete dentures

What does this study involve?
The participants are interviewed and observed immediately after receiving their dentures. After selected and appropriate interventions either on the base of the dentures or the surfaces of the artificial teeth, the patients are examined and interviewed again to complete a quality of life questionnaire after 90 days, 5 years and 9-10 years.

What are possible risks or benefits to the patients?
The study findings should show how to improve patients' satisfaction with their dentures. Generally, the patients are treated with conventional methods. There are no possible dangers and risks of the denture treatment, except when patients require insertion of implants into the jawbone.

Where is the study run from?
This study is run from towns and regional medical centers in central Bosnia

When is this study starting and how long it will last?
September 2016 to September 2019

Who is funding this study?
The Faculty of Pharmacy and Medicine and Dental Medical Center in Travnik (Bosnia)

Who is the main contact?
Associate Professor Srđan D. Poštić
sdposticdent@yahoo.com

Contact information

Type(s)
Scientific

Contact name
Prof Srđan Poštić

ORCID ID
http://orcid.org/0000-0001-9640-3282

Contact details
Rankeova 4
Beograd
Serbia
11000

Type(s)
Scientific

Contact name
Prof Srđan Poštić

Contact details
Slavka Gavrančića 17
Travnik-Dolac na Lašvi
Bosnia and Herzegovina
72270

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
03-67-1/14

Study information

Scientific Title
OHIP study in institutionalized and non-institutionalized terminally edentulous and edentulous complete denture wearers in Central Bosnia

Study objectives
The study hypothesis is that additional interventions on the acrylic complete dentures will provide benefit in oral quality of life and long-lasting treatment effects for denture wearers.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the FZF-Pharmaceutical-Health Faculty in Travnik, B and H Federation, 03/03 /2014, ref: 03-67-1/14

Study design
Multi-centre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Quality of life and quality of oral condition

Interventions
The first study arm
The first study arm is related to small interventions on the base of the acrylic denture by removal of small amounts of polymerized acrylic within existing denturing bases towards opposing peak of edentulous ridges as well as small corrections of occlusion (occlusal corrections based on an intensity of the marks on occlusal surfaces of artificial teeth using 60 µm and 40 µm articulating papers) (Other: BK 09 Blue Bausch Thin Articulating Papers 40 microns and BK-17 Blue Bausch Thin Articulating Papers Item #/Vendor: 310098 / BK 17-0024"/60 microns, Bausch dental GmbH&Co, Koln, Germany, EU). The first study arm is expected to be applied not only for the great majority of a patients, but probably for all of the patients of this study (n=129). The randomization process will follow subjective remarks and objections of patients, as well as objective findings of the investigator-specialist of dental prosthetic. Follow-ups will be tracked immediately after the baseline (T=0), and in the initial beginning period of 1, 2, 3, 4, up to 9 months after delivery and positioning of the dentures in the mouth of the patients.

The second study arm
Initially corrected existing bases of the complete acrylic dentures will be either relined with soft silicone-based denture liner (Other: Major Total Soft, polyvinyl siloxane liner, Major Prodotti, Dentari S.p.A., Italy, EU) and then, after necessary period of adaptation (up to two months) rebased (Other: Rebasing material: Akrilat- R, self-curing acrylate for reparations, Laser Dental Products, Serbia, Europa) on selected area of the base of the dentures, or rebasing would have been primarily and only conducted using auto-curing acrylate (Other-. Active Comparator: Denture liner autopolymerizing resin-cooliner- rebasing material: Akrilat- R, self-curing acrylate for reparations, Laser Dental Products, Serbia, Europa), with chairside procedures. The randomization process will be based on subjective demands and objective findings respecting specific needs or conditions of edentulous patients. It is expected that more than 1/3 of patients (n=50) will go through this procedure in the period of 3 years. Follow ups will be initially after applying of the second study arm interventions, and then after 5 and after 9-10 years respecting baseline (T=0).

The third study arm
The third study arm is optional. It is related to additional positioning of endooseal implants (Other: Astra TECH Implant System or Ankylos Dentsply Friadent, DENTSPLY Implants Europa) in edentulous jaws – only the lower one, or only the upper ones, or the upper and the lower jaws, for selected patients. Procedure: Insertion of two screw type dental implants into jaw bone. Superstructure for these implants will be ball retainers for every solitary endooseal implant. The randomization process will follow subjective remarks and objections of a patients, as well as objective findings of the investigator-specialist of dental prosthetic and outcome accessor (expected number of a patients n=11). Randomization process will be ultimately by the presence or absence of osteopenia/osteoporosis in the jaws, bone quality, allergic propensity, and additional needs for local jaw-bone augmentation or other. Follow ups will be initially after applying of the third study arm interventions, and then after 9-10 years respecting baseline (T=0) i.e. at the end of this study. Patient satisfaction is assessed with the OHIP-EDENT questionnaire validated in Bosnian (Serbian version) language.

Intervention Type
Mixed

Primary outcome measure
Oral health-related quality of life, assessed using the OHIP EDENT questionnaire at baseline, 90 days, 5 years and 9-10 years

Secondary outcome measures
Occlusal corrections measured using articulating paper immediately after the baseline, 1, 2, 3, 4, up to 9 months

Overall study start date
01/09/2016

Completion date
01/09/2019

Eligibility

Key inclusion criteria

1. Edentulous in both jaws
2. Complete denture wearers
3. Clinically acceptable occlusal relationships
4. Healthy mucosa (with no signs of inflammation, traumatic lesions, candidiasis, hyperplasia or tumors)

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
129

Total final enrolment
117

Key exclusion criteria
1. Residual vertical bone height less than 10 mm
2. No attached mucosa in any region of mandible (type E)
3. Dentures with deteriorated intaglio surfaces
4. Dentures with large pre-existing fractures
5. Dentures with severely altered occlusal vertical dimension
6. Dentures with unsatisfactory occlusions
7. Neurological diseases
8. Lack of motor coordination
9. Difficulty of understanding instructions and the conditions of the study
10. Patients with residual roots, cysts or bone spicules
11. Patients with allergies to methyl methacrylate or silicone
12. Knife-edge mandibular ridges

Date of first enrolment
01/04/2017

Date of final enrolment
23/04/2018

Locations

Countries of recruitment
Bosnia and Herzegovina

Study participating centre

Hospital in Travnik
Travnik
Bosnia and Herzegovina
72270

Study participating centre
Hospital Zenica
Zenica
Bosnia and Herzegovina
72000

Study participating centre
Hospital Vitez
Vitez
Bosnia and Herzegovina
72250

Study participating centre
Federal Medical Ambulance in Bugojno
Bugojno
Bosnia and Herzegovina
70230

Sponsor information

Organisation
Medical Centar

Sponsor details
Slavka Gavrančića 17
Travnik
Bosnia and Herzegovina
72270

Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
University/education

Funder Name
Faculty of Pharmacy and Health, Travnik

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed dental Journal.

Intention to publish date
01/09/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publically available repository

Preprint results in https://doi.org/10.21203/rs.3.rs-117922/v1 (added 02/03/2021)

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	20/09/2020	04/03/2021	Yes	No
Protocol file			29/09/2022	No	No
Results article	Psychometric properties of ohip-edent b&h for conventional complete denture wearers	10/01/2023	23/01/2023	Yes	No