

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparing satisfaction level of edentulous patients with bilateral balanced, lingualized and buccalized denture articulations and canine guidance nonbalanced denture articulations

Protocol summary

Study aim

The aim of this study was to compare patient satisfaction with four types of denture occlusion.

Design

In this study, 120 patients edentulous and criteria of the study referred to dental school Kermanshah are selected. The participants were randomly selected. The test was carried out in Phase 2-3.

Settings and conduct

Patients referring to Kermanshah Dentistry School are classified in four groups. In each group a set of complete dentures was made for each patient. The studied occlusions were: 1- bilateral balanced occlusion in which the most number of the teeth are in contact with all mandible movements, 2- lingualized occlusion in which just lingual cusps of maxillary teeth are the only ones in contact with the central fossa of mandibular teeth but the buccal cusps do not have any contact, 3- buccalized occlusion, the newfound occlusion in this study, in which just buccal cusps of mandibular teeth are in contact with the central fossa of maxillary teeth but the lingual cusps do not have any contact. 4- canin guidance occlusion teeth are arranged that during side movements there is contact only on worker side of canine and premolar teeth and molar teeth of worker side and all teeth of balance side are out of contact. After denture delivery and examinations after a day and a week, the satisfaction level of the patient was assessed at the end of month using a questionnaire. In this double blind study patients and researchers were not aware of the details and method of randomization. Stratified randomization was used in this study as a method of randomization.

Participants/Inclusion and exclusion criteria

edentulous patients; at least 3 month past from the last teeth extraction; no severe resorbed ridge; angle class 1 or mild class 2/3 jaw relation; signing the informed consent
Exclusion criteria: uncontrolled systemic

disease; mental problems; unwillingness to keep on the study

Intervention groups

1- bilateral balanced occlusion in which the most number of the teeth are in contact with all mandible movements. 2- lingualized occlusion in which just lingual cusps of maxillary teeth are the only ones in contact with the central fossa of mandibular teeth but the buccal cusps do not have any contact. 3- buccalized occlusion, the newfound occlusion in this study, in which just buccal cusps of mandibular teeth are in contact with the central fossa of maxillary teeth but the lingual cusps do not have any contact. 4- canin guidance occlusion teeth are arranged that during side movements there is contact only on worker side of canine and premolar teeth and molar teeth of worker side and all teeth of balance side are out of contact.

Main outcome variables

Increasing patients' satisfaction and obtaining more complete information about this occlusion to increase the performance of artificial teeth.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT2016021326538N1**

Registration date: **2016-05-12, 1395/02/23**

Registration timing: **registered_while_recruiting**

Last update: **2018-01-05, 1396/10/15**

Update count: **1**

Registration date

2016-05-12, 1395/02/23

Registrant information

Name

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Name of organization / entity

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Recruitment status**Recruitment complete****Funding source**

Kermanshah University of Medical Sciences

Expected recruitment start date

2015-09-27, 1394/07/05

Expected recruitment end date

2017-11-11, 1396/08/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing satisfaction level of edentulous patients with bilateral balanced, lingualized and buccalized denture articulations and canine guidance nonbalanced denture articulations

Public title

Comparing satisfaction level of edentulous patients by four types of occlusal scheme in complete denture

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Edentulous patients At least 3 month past from the last teeth extraction No sever resorbed ridge; Angle class 1 or mild class 2/3 jaw relation Signing the informed consent

Exclusion criteria:

Uncontrolled systemic disease Mental problems Unwillingness to keep on the study

AgeFrom **50 years** old to **80 years** old**Gender**

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample sizeTarget sample size: **120****Randomization (investigator's opinion)**

Randomized

Randomization description

En The sampling method is simplified randomly. A line is

generated and 120 people are randomly selected by numbers. According to Cochran's formula, a probability error of 5% was calculated for a sample size of 120.

Blinding (investigator's opinion)

Double blinded

Blinding description

En In this double blind study patients and researchers were not aware of the details and method of randomization. Stratified randomization was used in this study as a method of randomization.

Placebo

Not used

Assignment

Parallel

Other design features

In this double blind study patients and researchers were not aware of the details and method of randomization. Stratified randomization was used in this study as a method of randomization.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Kermanshah University of Medical Sciences

Street address

Ethics Committee, Department of Research and Technology, Central Building, Shahid Beheshti Boulevard, Kermanshah

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6715847141

Approval date

2017-09-06, 1396/06/15

Ethics committee reference number

IR.KUMS.REC.1396.300

Health conditions studied**1****Description of health condition studied**

Edentulous

ICD-10 code

k06.9

ICD-10 code description

Disorder of gingiva and edentulous alveolar ridge, unspecified

Primary outcomes

1

Description

Patients' Satisfaction

Timepoint

After 1 Month

Method of measurement

Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Making a set of complete denture with new Buccalized occlusion in that in this type of occlusion just buccal cusps of mandibular teeth are in contact with the central fossa of maxillary teeth whereas the lingual cusps do not have any contacts.

Category

Treatment - Other

2

Description

Making a set of complete denture with Lingualized occlusion in that in this type of occlusion lingual cusps of maxillary teeth are the only ones in contact with the central fossa of mandibular teeth but the buccal cusps do not have any contacts.

Category

Treatment - Other

3

Description

Making a set of complete denture with Balanced bilateral occlusion in that in this type of occlusion the most number of the tooth must be in contact at the all of mandible movement.

Category

Treatment - Other

4

Description

Making a set of complete denture with canine guidance occlusion that can be contacted during sidewalks only on the side of the worker of the canines and the molars, and the molar teeth of the worker side and all the teeth on the balancing side are out of.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

The school of Dentistry, Kermanshah University of Medical Sciences

Full name of responsible person

Mohaddese Arabzade

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The school of Dentistry, Kermanshah University of Medical Sciences, kermanshah, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Kermanshah University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Kermanshah University of Medical Sciences

Full name of responsible person
Mohaddese Arabzadeh

Position
Under graduated Student of Dentistry

Latest degree
Medical doctor

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available