Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

En 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 Phase2-3.

Settings and conduct

En Patients referring to Kermanshah Dentistry School are classified in four group.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 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

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

En 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

Hedaiat Moradpoor

Name of organization / entity
Kermanshah University of Medical Siences
Country
Iran (Islamic Republic of)
Phone
+98 83 3729 6910
Email address
h.moradpour@kums.ac.ir

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
Age
From **50 years** old to **80 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target 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
City
Kermanshah
Province
Kermanshah
Postal code
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
Street address
The school of Dentistry, Kermanshah University of Medical Sciences, kermanshah, Iran
City
Kermanshah
Province
Kermanshah
Postal code
6713954658
Phone
+98 83 4512 6083
Email
fatemeh.salari.dent1@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Farid Najafi
Street address
Vice Chancellor for Research Kermanshah University of Medical Sciences, Central building, Shahid Beheshti Boulevard, Kermanshah
City
Kermanshah
Province
Kermanshah
Postal code
6715847141
Phone
+98 83 3729 6591
Email
fnajafi@kums.ac.ir
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

Street address
The school of Dentistry, shariati Street, Kermanshah

City
Kermanshah

Province
Kermanshah

Postal code
6713954658

Phone
+98 837277030

Fax

Email
arabzade.m50@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Kermanshah University of Medical Sciences

Full name of responsible person
Hedayat Moradpour

Position
Prosthodontics Specialist

Latest degree
Specialist

Other areas of specialty/work
Dentistry

Street address
Department of Prosthodontics, The school of Dentistry, Kermanshah University of Medical Sciences , Iran

City
Kermanshah

Province
Kermanshah

Postal code
6713954658

Phone
+98 83 3729 6910

Fax

Email
h.moradpour@kums.ac.ir

Web page address

Person responsible for updating data

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
Dentistry

Street address
ایران، کرمانشاه، دانشگاه علوم پزشکی کرمانشاه، دانشکده دندانپزشکی

City
Kermanshah

Province
Kermanshah

Postal code
6713954658

Phone
+98 83 4512 6083

Fax

Email
arabzade.m50@gmail.com

Web page address

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