

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Assessment of adherence, oral tissue sensitivity and satisfaction level of patients using Rozhin and Corega company`s denture adhesives

Protocol summary

Study aim

Assessment of adherence, oral tissue sensitivity and satisfaction level of patients using Rozhin and Corega company`s denture adhesives

Design

Clinical trials, with parallel groups, Triple-blinded with randomized sampling among individuals referring to the Tabriz Dental faculty. The patients, evaluator and student are not aware of the type of adhesive. By statistical analysis, the sample size will include 52 people that will be divided into two groups (n = 26) of the recipients of Rojin glue and Corega adhesives. Patients are taught how to use the denture adhesives. In this way, the patient attaches the amount written on the product to three parts of the denture away from the edges, once a day. After 24hr, 3, 7 and 30 days will be followed. Patient is examined for tissue sensitivity, taste and smell of the adhesive, ability to clean and level of satisfaction.

Settings and conduct

52 number of patients divided into two groups: adhesives of Rojin and Corega. After 24hr, 3, 7 and 30 days will be followed. Patient is examined for tissue sensitivity, taste and smell of the adhesive, ability to clean and level of satisfaction. The patients, evaluator and student are not aware of the type of adhesive.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with grade 3 and 4 of the Periodontal Disease Index (PDI). Adaptable Denture. Use of denture for maximum of 5 years. Exclusion criteria: Patients with oral ulcers or lesions, history of allergies, severe xerostomia.

Intervention groups

1: Rojin's denture adhesives 2: Corega's denture adhesives

Main outcome variables

Tissue sensitivity, taste and smell of adhesive, cleaning ability, adhesion and satisfaction of patient

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200218046544N1**

Registration date: **2020-04-10, 1399/01/22**

Registration timing: **registered_while_recruiting**

Last update: **2020-04-10, 1399/01/22**

Update count: **0**

Registration date

2020-04-10, 1399/01/22

Registrant information

Name

Vahid Fakhrzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3335 5965

Email address

fakhrzadehv@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-04, 1399/01/16

Expected recruitment end date

2020-04-18, 1399/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of adherence, oral tissue sensitivity and satisfaction level of patients using Rozhin and Corega company's denture adhesives

Public title

Evaluate the quality of Rozhin and Corega company's denture adhesives

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Using of artificial dentures Satisfaction to participate in the study Patients with grade 3 and 4 of the Periodontal Disease Index(PDI) Adaptable Denture Use of denture for maximum of 5 years

Exclusion criteria:

severe xerostomia Patients with oral ulcers History of allergies Having red or white oral lesions

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: 52

Randomization (investigator's opinion)

Randomized

Randomization description

Sampling Method is randomly Available among Individuals referring to The Department of Prosthodontics of Tabriz Dental faculty. The randomization Method is simple and the Unit is individual, our Tool for randomization is the randomized Number Chart.

Furthermore, the Allocation of adhesives to Patients is done Randomly. To do this, the two types of adhesives are randomly recorded by a non-partner by numbering the numbers one to 52 and placed in tubes that are exactly the same shape and size. Then it is placed in a bag and stirred. Then, a tube is randomly removed from bag and used for each patient. None of the patients are aware of their adhesive type and the other patient. The evaluator, the student, and the principal are not aware of the type of adhesive .

Blinding (investigator's opinion)

Triple blinded

Blinding description

The present study is triple-blinded. None of the patients are aware of the type of their adhesive and the other patient. The evaluator, the student, and the principal investigator are not aware of the type of adhesive

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Floor2, Central Building No.2, Tabriz University of Medical Sciences, Golgasht St.

City

Tabriz

Province

East Azarbaijan

Postal code

5166614711

Approval date

2020-01-20, 1398/10/30

Ethics committee reference number

IR.TBZMED.REC.1398.1123

Health conditions studied

1

Description of health condition studied

Prosthodontic

ICD-10 code

Fitting an

ICD-10 code description

Z46.3

Primary outcomes

1

Description

The Intensity of tissue sensitivity

Timepoint

After 24 hours,three days,one week and one month

Method of measurement

Measurement of tissue sensitivity based on three criteria including of oral irritation, erythema or ulcer

2

Description

Taste and smell of adhesive

Timepoint

After 24 hours,three days,one week and one month

Method of measurement

According to the questionnaire

3

Description

Cleaning ability

Timepoint

After 24 hours,three days,one week and one month

Method of measurement

According to the questionnaire from 1 to 10

4**Description**

Satisfaction

Timepoint

After 24 hours,three days,one week and one month

Method of measurement

According to the questionnaire from 1 to 10

5**Description**

The amount of adhesion

Timepoint

After 24 hours,three days,one week and one month

Method of measurement

According to the questionnaire from 1 to 10

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention Group 1: Patients are taught how to use Rojin Company . (Rojin Pharmaceutical Health Company, Tabriz)denture adhesive. In this way, the patient attaches the amount written on the product to three parts of the denture away from the edges,once a day.

Category

Treatment - Drugs

2**Description**

Intervention Group 2: Patients are taught how to use Corega(GlaxoSmithKline Co, Ireland)denture adhesive. In this way, the patient attaches the amount written on the product to three parts of the denture away from the edges,once a day

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Tabriz University of Medical Sciences, Dentistry Faculty, Department of Prosthodontics

Full name of responsible person

Dr Vahid Fakhzadeh

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Building No.2, Dental Faculty, Tabriz University of

Medical Sciences, Golgasht St.

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Dr.Mohammad Samiei

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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

Tabriz 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**

Tabriz University of Medical Sciences

Full name of responsible person

Dr.Vahid Fakhzadeh

Position

Assistant professor of Prosthodontics

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Vahid Fakhrzadeh

Position

Assistant professor of Prosthodontics

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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Position

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Latest degree

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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