

# 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

**Street address**

Building No.2, Dental Faculty, Tabriz University of

Medical Sciences, Golgasht St.

**City**

Tabriz

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**Postal code**

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**Phone**

+98 41 3335 5965

**Email**

v.fakhzadeh@gmail.com

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

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr.Mohammad Samiei

**Street address**

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

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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

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Assistant professor of Prosthodontics

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Specialist

**Other areas of specialty/work**

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

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr. Vahid Fakhrzadeh

**Position**

Assistant professor of Prosthodontics

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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