

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 2026

### Comparison of the effect of dental injuries due to trauma during electroconvulsive therapy with cotton roll and prefabricated mouthguard protection

#### Protocol summary

##### Study aim

Comparison of the effect of dental injuries due to trauma during electroconvulsive therapy with cotton roll and prefabricated mouth guard protection

##### Design

This study will be performed as a clinical trial with a control group with parallel single-blind randomized groups on 30 patients. A random number table in sealed envelopes will be used for randomization. patients will be divided in two groups intervention group( prefabricated mouth guard ) and control group (cotton roll between teeth)

##### Settings and conduct

Two checklists are prepared for each patient to record data before and after ECT. All patients will be examined by a single dentist. All teeth, including healthy, root treated, deep and superficial caries, deep amalgam and composite restorations, are recorded in the checklist. If a teeth is not maintainable, the patient will be informed to be fully examined and necessary measures to reduce the risk of aspiration during the ECT process. During ECT, a cotton roll or prefabricated protector will be used according to the group. Examination after ECT is performed by the same dentist and he is not aware of the grouping, and again after ECT, he will record fracture, loose teeth and filled teeth separately in the checklist. Normally, cotton rolls are used for these patients, so this group is considered as the control group.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with psychological disorder needing ECT and having at least 20 teeth exclusion criteria: Major temporomandibular disorders and patients unable to cooperate

##### Intervention groups

1- intervention group: prefabricated mouth guard 2- control group: cotton roll between teeth

##### Main outcome variables

Fractured teeth, loosening of teeth or increase in loosening degree and fracture of filled teeth

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210822052251N3**

Registration date: **2022-07-21, 1401/04/30**

Registration timing: **prospective**

Last update: **2022-07-21, 1401/04/30**

Update count: **0**

##### Registration date

2022-07-21, 1401/04/30

##### Registrant information

##### Name

Neda Yasamineh

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 3337 4991

##### Email address

yasamineh@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-08-01, 1401/05/10

##### Expected recruitment end date

2022-09-22, 1401/06/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
Comparison of the effect of dental injuries due to trauma during electroconvulsive therapy with cotton roll and prefabricated mouthguard protection

**Public title**  
Comparison of the effect of dental injuries due to trauma during electroconvulsive therapy with cotton roll and prefabricated mouthguard protection

**Purpose**  
Prevention

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Patient or legal guardian having consent to participate  
Having psychological disorders needing electroconvulsive therapy  
Having at least 20 teeth  
**Exclusion criteria:**  
Major temporomandibular disorder  
Patient unable to cooperate

**Age**  
No age limit

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**

- Outcome assessor

**Sample size**  
Target sample size: **30**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Individuals will be randomly assigned to one of two study groups with the help of a random number table and will receive the intervention of the allocated group. For allocation concealment, the method of sealed opaque envelopes which are numbered sequentially will be used. In this method, each random sequence is recorded on a card. Finally, the lids of the letter envelopes will be glued and placed inside a box. At the beginning of the registration of participants, according to the order of entry of eligible participants to study, one of the envelopes will be opened in order and the assigned group of the participant will be revealed.

**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**  
only the dentist examining the teeth will be blind and will not know patients groups and will examine the patients before and after the intervention. The patient or legal guardian won't be blind because the intervention is recognizable, though the allocation will be randomized.

**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

Vice chancellor of research, Tabriz university of medical sciences, Golghasht avenue

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5166614711

#### Approval date

2022-06-01, 1401/03/11

#### Ethics committee reference number

IR.TBZMED.REC.1401.222

## Health conditions studied

### 1

#### Description of health condition studied

patients needing electroconvulsive shock therapy

#### ICD-10 code

F33.3

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

tooth fracture

#### Timepoint

immediately after intervention

#### Method of measurement

clinical examination and counting teeth

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Use of pre-fabricated mouthguard

#### Category

Treatment - Devices

## 2

### Description

Control group: Use of cotton roll

### Category

Treatment - Devices

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Tabriz Razi hospital

**Full name of responsible person**

Seyed Gholamreza Nourazar

**Street address**

Razi training Center, Shahid Bakeri boulevard (Elgoli)

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code****Phone**

+98 41 3380 4486

**Email**

Razi.Hospital@tbzmed.ac.ir

**Web page address**

<https://prazif.tbzmed.ac.ir/>

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Parviz Shahabi

**Street address**

Vice chancelor for research, No 2 Central Building,  
Tabriz University of Medical Sciences, Golghasht  
Street

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5165665931

**Phone**

+98 41 3334 4280

**Email**

research-vice@tbzmed.ac.ir

**Web page address**

<https://researchvice.tbzmed.ac.ir/>

**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**

Neda Yasamineh

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

**Street address**

Entrance 4, Tabriz university of medical sciences,  
Golghasht avenue

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5166614711

**Phone**

+98 41 3335 5965

**Email**

dent.fac@tbzmed.ac.ir

**Web page address**

<https://dentistryfac.tbzmed.ac.ir/>

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Neda Yasamineh

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

**Street address**

Prosthesis section, Dentistry Faculty, Golgasht Street,  
Tabriz, Iran

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**  
5166614711  
**Phone**  
+98 41 3334 6977  
**Email**  
yasamineh@gmail.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Tabriz University of Medical Sciences  
**Full name of responsible person**  
Neda Yasamineh  
**Position**  
Assistant professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Dentistry  
**Street address**  
University street ,faculty of dentistry,tabriz university  
of medical sciences,tabriz,iran  
**City**  
Tabriz  
**Province**  
East Azarbaijan  
**Postal code**  
5166614711  
**Phone**  
+98 41 3337 4991  
**Fax**  
**Email**  
yasamineh@gmail.com

## 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**  
Yes - There is a plan to make this available

**Statistical Analysis Plan**  
Not applicable

**Informed Consent Form**  
Yes - There is a plan to make this available

**Clinical Study Report**  
Yes - There is a plan to make this available

**Analytic Code**  
Not applicable

**Data Dictionary**  
Not applicable

**Title and more details about the data/document**  
The results of the study will be reported in the form of article and student theses, and raw data can be provided upon request.

**When the data will become available and for how long**  
Access period starts 6 months after the results are published

**To whom data/document is available**  
Researchers working in academic and scientific institutes, doctors and dentists

**Under which criteria data/document could be used**  
Use of the data for further research or treatment is permitted.

**From where data/document is obtainable**  
Katayoun Katebi 00984133355965 Department of oral medicine, Tabriz faculty of dentistry  
katebik@tbzmed.ac.ir

**What processes are involved for a request to access data/document**  
The applicant sends request via email and information and data will be sent to email

**Comments**