Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jul 2026

The assessment of pain perception and compliance of orthodontic patients treated with heavy and medium intermaxillary elastics

Protocol summary

Study aim
The comparison of pain perception and compliance of orthodontic patients treated with heavy and medium intermaxillary elastics

Design
A randomized clinical trial using random numbers table, two parallel groups and 53 patients in each group, without blindness

Settings and conduct
The elastics will be placed from the canine tooth to the first molar. Patients in the first group will receive medium elastic and patients in the second group will receive heavy elastic. Patients' pain intensity will be recorded on the same day, one, four, and fourteen days after receiving intermaxillary elastics by using the visual analog scale. A researcher-made questionnaire will be used based on Likert scale to measure patient compliance.

Participants/Inclusion and exclusion criteria
Inclusion criteria is to have the consent to participate in the study. Exclusion criteria is to have systemic or mental illness and addiction to alcohol or any psychoactive substance.

Intervention groups
This study has two groups. Patients in the first group will be treated with medium intermaxillary elastic and the second group will be treated with heavy intermaxillary elastic.

Main outcome variables
Pain intensity; Patient compliance

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150628022951N5**
Registration date: **2018-05-21, 1397/02/31**
Registration timing: **registered_while_recruiting**
Last update: **2018-05-21, 1397/02/31**
Update count: **0**

Registration date
2018-05-21, 1397/02/31

Registrant information

Name
milad Ghanizadeh

Name of organization / entity
Tabriz University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-01-21, 1396/11/01

Expected recruitment end date
2018-07-11, 1397/04/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The assessment of pain perception and compliance of orthodontic patients treated with heavy and medium intermaxillary elastics

Public title
The comparison of pain perception and compliance of patients treated with orthodontic elastics

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Having the consent to participate in the study

Exclusion criteria:

Having a systemic or mental disease Addiction to alcohol or any psychoactive substance

Age

From **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **106**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, a simple randomization method will be used. Each person will be assigned a code, and according to the random number table, each person will be placed in a group.

Blinding (investigator's opinion)

Not blinded

Blinding description

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

Tabriz University of Medical Sciences, Golgasht Avenue, Azadi Street,Tabriz

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Province

East Azarbaijan

Postal code

5166614766

Approval date

2018-03-01, 1396/12/10

Ethics committee reference number

IR.TBZMED.REC.1397.106

Health conditions studied

1

Description of health condition studied

Jaw discrepancy

ICD-10 code

K07.1

ICD-10 code description

Anomalies of jaw-cranial base relationship

Primary outcomes

1

Description

Pain intensity

Timepoint

on the same day, one, four, and fourteen days after receiving intermaxillary elastic

Method of measurement

Visual analog scale

Secondary outcomes

1

Description

Patient compliance

Timepoint

on the same day, one, four, and fourteen days after receiving intermaxillary elastic

Method of measurement

Researcher-made questionnaire

Intervention groups

1

Description

First intervention group: Receiving medium intermaxillary elastic

Category

Treatment - Devices

2

Description

Second intervention group: Receiving heavy intermaxillary elastic

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz Dental Faculty

Full name of responsible person

Zahra Mardani

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Sponsors / Funding sources

1

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Name of organization / entity
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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
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Assistant professor
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

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
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Demographic information of patients and data related to the outcomes of the study (pain intensity and patient compliance) will be shared.

When the data will become available and for how long
The access period starts 6 months after the results are published.

To whom data/document is available
Researchers working in academic and scientific institutions

Under which criteria data/document could be used
Sharing data for meta-analysis

From where data/document is obtainable
Please contact Dr. Zahra Mardani by e-mail: z_mardani422@yahoo.com

What processes are involved for a request to access data/document
After ensuring that your claim is true, these data will be sent to you.

Comments