

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Sep 2026

### Effect of bionator treatment on skeletal and dental changes among class II patients

#### Protocol summary

##### Summary

aim: Effect of bionator treatment on skeletal and dental changes among class II patients study design: randomized, single blind, no placebo inclusion criteria: age 12-9 years; with dental and skeletal Class II malocclusion, Exclusion criteria: uncooperative children sample size: 17 patients (8 girls and 9 boys) intervention studied: bionator appliance intervention time: 5-19 months

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015112525242N1**

Registration date: **2016-02-20, 1394/12/01**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-02-20, 1394/12/01

##### Registrant information

###### Name

Mehdi Rafiei

###### Name of organization / entity

Islamic Azad University of Isfahan (Khorasgan), Dental School

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 3535 4066

###### Email address

mehdi.rafiee@khuisf.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Investigator

##### Expected recruitment start date

2013-09-21, 1392/06/30

##### Expected recruitment end date

2014-10-22, 1393/07/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of bionator treatment on skeletal and dental changes among class II patients

##### Public title

Effect of bionator treatment on skeletal and dental changes among class II patients

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: age 12-9 years; with dental and skeletal Class II malocclusion, Exclusion criteria: uncooperative children

##### Age

From **84** years old to **81** years old

##### Gender

Both

##### Phase

N/A

##### Groups that have been masked

*No information*

##### Sample size

Target sample size: **17**

##### Randomization (investigator's opinion)

Randomized

##### Randomization description

##### Blinding (investigator's opinion)

Single blinded

## Blinding description

### Placebo

Not used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Islamic Azad University of Isfahan (Khorasgan), Dental School

##### Street address

Islamic Azad University of Isfahan (Khorasgan), Jay Street

##### City

Isfahan

##### Postal code

#### Approval date

2013-11-22, 1392/09/01

#### Ethics committee reference number

23810201900150

## Health conditions studied

### 1

#### Description of health condition studied

skeletal malocclusion Class II

#### ICD-10 code

K07.5

#### ICD-10 code description

Dentofacial functional abnormalities

## Primary outcomes

### 1

#### Description

malocclusion class II

#### Timepoint

3-4 weeks

#### Method of measurement

colis & conveyor

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

bionitir

## Category

Treatment - Devices

### 2

#### Description

control

#### Category

Treatment - Devices

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Islamic Azad University of Isfahan (Khorasgan), Dental School

##### Full name of responsible person

Mehdi Rafiei

##### Street address

##### City

Isfahan

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Islamic Azad University Isfahan (Khorasgan)

##### Full name of responsible person

Mehdi Rafiei

##### Street address

Islamic Azad University of Isfahan (Khorasgan), Dental School

##### City

Isfahan

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Islamic Azad University Isfahan (Khorasgan)

#### Proportion provided by this source

100

#### Public or private sector

empty

#### Domestic or foreign origin

empty

#### Category of foreign source of funding

empty

#### Country of origin

#### Type of organization providing the funding

empty

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Islamic Azad University of Isfahan (Khorasgan), Dental

School

**Full name of responsible person**

Mehdi Rafiei

**Position**

Orthodontics/phd

**Other areas of specialty/work**

**Street address**

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**Web page address**

**Person responsible for updating data**

**Contact**

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Islamic azad university Isfahan (Khorasgan)

**Full name of responsible person**

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afiei1359@gmail.com

**Web page address**

**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*