

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

Evaluation of the efficacy of tooth movement using Smilelign clear aligners in orthodontic patients

Protocol summary

Summary

Innovations in the appearance of orthodontic appliances may be a major factor in the increasing acceptability of orthodontic treatment for adults. Adults considering treatment now have a choice in the type of aesthetic appliance design including clear plastic aligners. This interventional study is designed to evaluate the treatment efficacy of clear aligners. Twenty patients will be selected nonrandomly among the patients referred to Kerman dentistry school. There is no control group in this study. Inclusion criteria will be: mild to moderate crowding; mild to moderate spacing; Class I molar relationship; patients of 13 years or over; permanent dentition without any pre-extraction or oral lesion. Exclusion criteria will be: patients in need of fixed appliance therapy and orthognathic surgery treatments; patients with systemic diseases, malformations and syndromes. Duration of treatment will be about 2 years. Final Virtual models that predict final teeth positions will be superimposed on virtual models achieved at the end of treatment. Efficacy analysis will be reported by Orthostudio software.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017061834617N1**
Registration date: **2017-07-27, 1396/05/05**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-07-27, 1396/05/05

Registrant information

Name

Mohammad Mousavi

Name of organization / entity

Kerman Medical University

Country

Iran (Islamic Republic of)

Phone

+98 34 3132 5700

Email address

nedasinaee@gmail.com

Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2017-07-23, 1396/05/01

Expected recruitment end date

2017-09-23, 1396/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the efficacy of tooth movement using Smilelign clear aligners in orthodontic patients

Public title

Evaluation of the efficacy of orthodontic tooth movement using clear aligners

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria will be: mild to moderate crowding; mild to moderate spacing; Class I molar relationship; patients of 13 years or over; permanent dentition without any pre-extraction or oral lesion. Exclusion criteria will be: patients in need of fixed appliance therapy or orthognathic surgery treatments; patients with systemic

diseases, malformations and syndromes.

Age

From **13 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Other

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research and Technology Vice-Presidency of Kerman
University of Medical Sciences

Street address

Tahmasb abad square, Kerman, Iran

City

Kerman

Postal code

1355576169

Approval date

2017-02-08, 1395/11/20

Ethics committee reference number

IR.KMU.REC.1395.821

Health conditions studied**1****Description of health condition studied**

Evaluation of the efficacy of tooth movement using
Smileign clear aligners in orthodontic patients

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Dental rotation

Timepoint

At the end of treatment

Method of measurement

Orthostudio software

2**Description**

Tipping of tooth crown

Timepoint

At the end of treatment

Method of measurement

Orthostudio software

3**Description**

Labiolingual crown torque

Timepoint

At the end of treatment

Method of measurement

Orthostudio software

4**Description**

Dental Intrusion/Extrusion

Timepoint

At the end of treatment

Method of measurement

Orthostudio software

Secondary outcomes**1****Description**

Failure in correction of dental crowding

Timepoint

At the end of treatment

Method of measurement

Orthostudio software

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

Orthodontic treatment using clear aligners

Category

Other

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

Orthodontic Department, Kerman Dental School

Full name of responsible person

Mohammad Mousvi, Postgraduate student of

Orthodontics

Street address

Orthodontic Department, Kerman Dental School,
Shafa Street, Kerman, Iran

City

Kerman

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Investigator

Full name of responsible person

Mohammad Mousavi

Street address

Orthodontic Department, Kerman Dental School,
Shafa Street, Kerman, Iran

City

Kerman

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Investigator

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

Kerman University of Medical sciences

Full name of responsible person

Mohammad Mousavi

Position

Postgraduate student of orthodontics

Other areas of specialty/work

Street address

Orthodontic Department, Kerman Dental School,
Shafa Street, Kerman, Iran

City

Kerman

Postal code

Phone

+98 34 3247 7033

Fax

Email

nedasinaee@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kerman University of Medical sciences

Full name of responsible person

Dr Neda Sinaee

Position

Assistant professor at Orthodontic department

Other areas of specialty/work

Street address

Orthodontic Department, Kerman Dental School,
Shafa Street, Kerman, Iran

City

Kerman

Postal code

Phone

+98 34 3247 7033

Fax

Email

nedasinaee@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Kerman University of Medical sciences

Full name of responsible person

Mohammad Mousavi

Position

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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