

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jul 2026

### Investigating the effect of ultrasound on prevention of relapse in severe crowding

#### Protocol summary

##### Study aim

Determining the rate of relapse after alignment & leveling in orthodontic patients treated with ultrasound compared to the control group

##### Design

Clinical trial with a control group, with parallel groups, double-blind, randomized. on 60 patients. The rand function of Excel software was used for randomization.

##### Settings and conduct

In this research, 60 patients with class 1 problem with severe crowding are selected. Patients should undergo fixed orthodontic treatment of both jaws with extraction of the first premolar tooth in both arches. Then the patients are randomly divided into two groups. All patients are molded with alginate at this stage (T0). Then one group is considered as the control group. In the second group, from twenty days before removing the arch wire, there is a low-intensity ultrasound with a frequency protocol of 1 MHz and an intensity of 100 mW/cm<sup>2</sup> and a duty cycle of 20% (in 1000 cycles per second, 200 us on and 800 us off), frequency 1 KHz And the time of 20 minutes is irradiated to the canine teeth and alveoli of this area in both jaws for 10 sessions in the middle of a day. After this two-month period, the upper and lower jaws are molded from the case and control groups. Molds are cast with orthodontic plaster and are considered as T1.

##### Participants/Inclusion and exclusion criteria

Patients with 1- systemic disease 2- improper oral hygiene 3- gingivitis or periodontal problems or deep caries that have spread to the cement enamel junction 4- taking drugs that affect bone metabolism such as drugs that prevent bone resorption 5- Conditions for which liposuction is contraindicated, such as (pregnancy, the presence of a malignant lesion in the irradiated area, etc.)

##### Intervention groups

In the intervention group, twenty days before removing the arch wire and after correcting the crowding, the

patient is treated with ultrasonic waves.

##### Main outcome variables

crowding

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20221028056331N1**

Registration date: **2022-11-25, 1401/09/04**

Registration timing: **prospective**

Last update: **2022-11-25, 1401/09/04**

Update count: **0**

##### Registration date

2022-11-25, 1401/09/04

##### Registrant information

##### Name

at-har nasseri mojarad

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 3625 5326

##### Email address

nasseri.mojarad@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-12-08, 1401/09/17

##### Expected recruitment end date

2023-03-20, 1401/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
Investigating the effect of ultrasound on prevention of relapse in severe crowding

**Public title**  
Investigating the effect of ultrasound on prevention of relapse in severe crowding

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Patients between 17-30 years old with severe crowding (more than 8 mm crowding) of two jaws have been subjected to fixed orthodontic treatment with the extraction of 4 first premolars of both jaws. Absence of systemic disease Proper oral hygiene Not suffering from conditions for which liposuction is contraindicated, such as (pregnancy, the presence of a malignant lesion in the irradiated area, etc.)  
**Exclusion criteria:**  
Non-cooperation of the patient to attend at specified times Gingivitis or periodontal problems or deep caries that have spread to the cement enamel junction Taking drugs that affect bone metabolism, such as drugs that prevent bone resorption

**Age**  
From **17 years** old to **30 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**

- Participant
- Data analyser

**Sample size**  
Target sample size: **60**

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

**Randomization description**  
Block randomization was done using blocks of 4. For this purpose, we benefited from the PASS 11 software, and thus people were assigned to two groups of 30.

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

**Blinding description**  
60 patients from the special clinic of Mashhad Faculty of Dentistry, who meet the conditions for entering the study, were included in the study with their consent and were randomly divided into two equal intervention and control groups. For patients in the intervention group, the device was used on, and for the control group, the device was turned off. Patients of both intervention and control groups, as well as the person analyzing the data, were blinded.

**Placebo**  
Used

**Assignment**

Other

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

ethics committee of mashhad university of medical science

##### Street address

vakil abad blv

##### City

mashhad

##### Province

Razavi Khorasan

##### Postal code

9117941909

#### Approval date

2022-05-28, 1401/03/07

#### Ethics committee reference number

IR.MUMS.DENTISTRY.REC.1401.021

## Health conditions studied

### 1

#### Description of health condition studied

dental relaps

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

1- Width of intercanin2- Intermolar width3- Arch length4- Arch Circumference5-Modified Little's irregularity index

#### Timepoint

Before the intervention and two months after removing the archwires

#### Method of measurement

Scanning dental cassettes and analyzing irregularities with computer software

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group:irradiation of ultrasonic waves on the soft tissue of the lips and around of it

**Category**

Treatment - Devices

2**Description**

Control group: using the device on the off mode

**Category**

Placebo

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

masshad special dental clinic

**Full name of responsible person**

athar nasseri mojarad

**Street address**

vakil abad Blvd

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**Province**

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**Postal code**

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**Web page address**<https://dentistry.mums.ac.ir>**Sponsors / Funding sources**1**Sponsor****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

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**Street address**

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**Fax****Email**

mail.mums@ac.ir

**Web page address**<https://dentistry.mums.ac.ir>**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

**Title of funding source**

vice chancellor for research of Mashhad 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**

Mashhad University of Medical Sciences

**Full name of responsible person**

athar nasseri mojarad

**Position**

resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dentistry

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

arezoo jahan bin

**Position**

professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

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Mashhad University of Medical Sciences

**Full name of responsible person**

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**Position**

resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dentistry

**Street address**

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**City**

mashhad

**Province**

Razavi Khorasan

**Postal code****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