

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Clinical comparison of Gelofen drug and low power diode laser effect on pain induced by orthodontic separator implementation

#### Protocol summary

##### Summary

The purpose of this study is to compare the effect of laser and Gelofen in reducing pain after separator placement . The study is double blind and the patients randomly select their group by taking a paper from pocket. The number of patients are 60 ranged between 13 -25 years old . An hour before separator placement 30 patients receive one dose of Gelofen and instantly after placement receive laser facade. The remaining 30 patients receive placebo and LLLT laser in the same way. Patients should not have systemic disease and also should not have history of orthodontic treatment. The primary outcome variable is the amount of pain reduction after separator placement .The second outcome variable is to compare the effect of laser and Gelofen in reducing pain after separator placement .

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016061316582N2**

Registration date: **2016-10-31, 1395/08/10**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-10-31, 1395/08/10

##### Registrant information

##### Name

Vahid Mollabashi

##### Name of organization / entity

Hamadan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 81 3835 2555

##### Email address

mollabashi@umsha.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for research and technology, Hamadan University of Medical Sciences

##### Expected recruitment start date

2016-03-19, 1394/12/29

##### Expected recruitment end date

2017-03-20, 1395/12/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Clinical comparison of Gelofen drug and low power diode laser effect on pain induced by orthodontic separator implementation

##### Public title

comparison of analgesic drug and laser effect on pain reduction after orthodontic separator implementation

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

Inclusion criteria: Patients between 13-25 years old; Female patients not to be pregnant; Patients with no orthodontic treatment history; Patients with no gelofen reaction history in the drug group; In the drug group the minimum weight should be 40 kg. Exclusion criteria: patients with history of systemic disease; Patients with periodontal disease, More than 3 mm Probing depth; Attached gingiva recession; Using antibiotic in drug group .

##### Age

From **13 years** old to **25 years** old

#### **Gender**

Both

#### **Phase**

N/A

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **60**

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

Randomized

#### **Randomization description**

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

Double blinded

#### **Blinding description**

#### **Placebo**

Used

#### **Assignment**

Parallel

#### **Other design features**

### **Secondary Ids**

empty

### **Ethics committees**

#### 1

##### **Ethics committee**

###### **Name of ethics committee**

Ethics committee, Hamedan University of Medical Sciences

###### **Street address**

Orthodontic Department, School of Dentistry, Shahid Fahmideh street, Hamedan

###### **City**

Hamedan

###### **Postal code**

38677-65178

###### **Approval date**

2016-06-11, 1395/03/22

###### **Ethics committee reference number**

IR.UMSHA.REC.1395.150

### **Health conditions studied**

#### 1

##### **Description of health condition studied**

orthodontic pain

##### **ICD-10 code**

K08.9

##### **ICD-10 code description**

Disorder of teeth and supporting structures, unspecified

### **Primary outcomes**

#### 1

##### **Description**

The pain after separator placement

#### **Timepoint**

Immediately after the intervention, 6 hours after intervention, 12 hours after intervention, 24 hours after intervention, 2 days after intervention, 3 days or more after intervention

#### **Method of measurement**

Questionnaire Modified McGill

### **Secondary outcomes**

empty

### **Intervention groups**

#### 1

##### **Description**

In drug group patients receive 400mg Gelofen an hour before placing separator between the contacts of maxillary molars and after placement using laser facade flash without therapeutic effect .

##### **Category**

Treatment - Drugs

#### 2

##### **Description**

In the laser group patients receive placebo of the Gelofen an hours before placement of separator between the contacts of maxillary molars. Immediately after separator placement laser will expose to three points of apex, mesial and distal. Laser properties include: Wavelength 940nm Exposure Time 20 seconde Exposure Dose 4j/cm2 Power 45 mw.

##### **Category**

Treatment - Other

### **Recruitment centers**

#### 1

##### **Recruitment center**

###### **Name of recruitment center**

Hamedan University of Medical Sciences

###### **Full name of responsible person**

Dr.Vahid Mollabashi

###### **Street address**

Departemant of Orthodontic, Dental Callege, Shahid Fahmide street, Hamedan

###### **City**

Hamedan

### **Sponsors / Funding sources**

#### 1

##### **Sponsor**

###### **Name of organization / entity**

Vice Chancellor for Research and Technology, Hamedan University of Medical Science

###### **Full name of responsible person**

Dr. Said Bashirian

**Street address**

School of Medicine, Shahid Fahmide Street, Hamedan

**City**

Hamedan

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Vice Chancellor for Research and Technology, Hamedan University of Medical Science

**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**

Hamedan University of Medical Sciences

**Full name of responsible person**

vahid mollabashi

**Position**

Assistant Professor

**Other areas of specialty/work**

**Street address**

Orthodontic Department, School of Dentistry, Shahid Fahmide Street, Hamedan

**City**

Hamedan

**Postal code**

38677-65178

**Phone**

+98 81 3838 0130

**Fax**

**Email**

vahidmolabashi@yahoo.com

**Web page address**

mollabashi@umsha.ac.ir

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Hamedan of Medical Science

**Full name of responsible person**

Dr.vahid mollabashi

**Position**

Assistant professor

**Other areas of specialty/work**

**Street address**

Hamedan, Shahid Fahmide Street, Dental Callege, Department of Orthodontic

**City**

Hamedan

**Postal code**

38677-65178

**Phone**

+98 81 3838 0130

**Fax**

**Email**

vahidmolabashi@yahoo.com

**Web page address**

mollabashi@umsha.ac.ir

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Hamadan University of Medical Sciences

**Full name of responsible person**

Dr.vahid mollabashi

**Position**

Assistant professor

**Other areas of specialty/work**

**Street address**

Orthodontic Department, School of Dentistry, Shahid Fahmide Street, Hamedan

**City**

Hamedan

**Postal code**

38677-65178

**Phone**

+98 81 3838 0130

**Fax**

**Email**

vahid.mollabashi@gmail.com

**Web page address**

mollabashi@umsha.ac.ir

## 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*