Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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

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Vahid Mollabashi
Name of organization / entity
Hamadan University of Medical Sciences
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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 between13-25 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 seprator 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

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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

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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