Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of wound healing after Epulis Fissuratum surgery with surgical blade and new generation of CO2 laser in patients with bilateral lesion

Protocol summary

Summary

The purpose of this study is comparing the removal of Epulis Fissuratum with surgical blade and CO2 laser. 19 patients with symmetric Epulis Fissuratum lesion in the anterior region of the jaws that refer to Periodontology Department of Dentistry Faculty of Hamadan University of Medical Sciences in 2016-2017 will be selected. Randomly one part of the lesions will be removed with surgical blade as control groups and the other part of the lesions will be removed with CO2 laser as test groups. Suturing would be done if needed. Randomization will be done by a flip of a coin. The time of surgical procedure would be measured for both groups. Assessing of wound healing will be done on day 7 and 14 after surgery. Also vestibular depth would be assessed in both groups on day 14.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016071124969N2**
Registration date: **2016-07-17, 1395/04/27**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-07-17, 1395/04/27

Registrant information

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Sara Torabi
Name of organization / entity
Hamadan University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Hamadan University of Medical Sciences

Expected recruitment start date

2016-07-10, 1395/04/20

Expected recruitment end date

2016-09-10, 1395/06/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of wound healing after Epulis Fissuratum surgery with surgical blade and new generation of CO2 laser in patients with bilateral lesion

Public title

Comparison of Epulis Fissuratum surgery with conventional surgery and laser

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Epulis Fissuratum lesion in the anterior region of jaws Exclusion criteria: Patients with systemic disease ; Smoking ; Unacceptable oral hygiene ; Radiotherapy/chemotherapy

Age

From **50 years** old to **70 years** old

Gender

Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **38**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Hamadan University of Medical Sciences
Street address
In Front of Mardom Park, Shahid Fahmide Avenue, Hamadan
City
Hamadan
Postal code
654178-38741
Approval date
2015-12-16, 1394/09/25
Ethics committee reference number
IR.UMSHA.REC.1394.258

Health conditions studied

1

Description of health condition studied
Epulis Fissuratum
ICD-10 code
K06.2
ICD-10 code description
Gingival and edentulous alveolar ridge lesions associated with trauma

Primary outcomes

1

Description
The time of surgery
Timepoint
during surgery
Method of measurement
stopwatch

2

Description
wound healing
Timepoint
on day 7 and 14 after surgery
Method of measurement
according to check list criteria

3

Description
vestibular depth
Timepoint
on day 14 after surgery
Method of measurement
by probe

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: surgery of Epulis Fissuratum lesion with CO2 laser (DEKA device) with 50 Hz frequency and 3 millisecond puls duration
Category
Treatment - Surgery

2

Description
Control group: surgery of Epulis Fissuratum lesion with surgical blade number 15
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Dentistry Faculty of Hamadan University of Medical Sciences
Full name of responsible person
Sara Torabi
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Dentistry Faculty of Hamadan University of Medical Sciences, In front of Mardom Park, Shahid Fahmide Avenue, Hamadan
City
Hamadan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research, Hamadan University of Medical Sciences
Full name of responsible person
Shahin Kasraei (Research Assistant)
Street address
Dentistry Faculty of Hamadan University of Medical Sciences
City
Hamadan
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, Hamadan University of Medical Sciences
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
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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