

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

comparison of cryosurgery and diode laser 810 nm for gingival depigmentation and recurrence

Protocol summary

Summary

The aim of this study is comparing the effectiveness and recurrence of diode laser 810 nm and cryosurgery for gingival depigmentation. The inclusion criteria is having gingival pigmentation of maxillary incisors and the exclusion criteria are that any diseases or systemic conditions or using any drugs causing gingival pigmentation. This study includes 12 patients aged 15 to 50 years. For further evaluation photographs will be taken before and after treatment within the same position and light. The color analysis will be done using Adobe Photoshop software. Patients will be treated randomized split mouth, with diode laser 810 nm -2w of half of maxillary gingiva and on the opposite side cryosurgery will be done. treatment will be done under topical anesthesia. The laser beam would be activated using the brush technique and in contact mode. Application period differs according to the degree of melanin pigmentation and epithelial thickness of treated area. The cryosurgery will be done on the opposite side with cotton swab. The swab will gently touch and rolled on the area for 10 to 15 seconds until disappear area of gingival pigmentation and looks frosty. All patients will be examined at 1,3 and 6 months after treatment

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017011732027N1**
Registration date: **2017-03-04, 1395/12/14**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-03-04, 1395/12/14

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Ahvaz Jundishapur University Of Medical Sciences-School Of Dental Medicine

Expected recruitment start date

2017-02-03, 1395/11/15

Expected recruitment end date

2017-02-25, 1395/12/07

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparison of cryosurgery and diode laser 810 nm for gingival depigmentation and recurrence

Public title

comparison of cryosurgery and diode laser for gingival depigmentation and recurrence

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: having physiologic hyperpigmentation in anterior maxillary site Exclusion criteria: having any disease causing hyper pigmentation; systemic condition

causing hyper pigmentation; using drugs causing hyperpigmentation ;smoking

Age

From **15 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **12**

Randomization (investigator's opinion)

N/A

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

Ahvaz Jundishapur University Of Medical Sciences

Street address

Ahvaz Jundishapur University Of Medical Sciences-
School Of Dental Medicine

City

Ahvaz

Postal code

Approval date

2016-06-21, 1395/04/01

Ethics committee reference number

IR.AJUMS.REC.1395.1186

Health conditions studied

1

Description of health condition studied

gingival Pigmantasion

ICD-10 code

K06.9

ICD-10 code description

Disorder of gingiva and edentulous alveolar ridge,
unspecified

Primary outcomes

1

Description

degree of pigmentation

Timepoint

befor treatment and 1, 3 and 6 months after treatment

Method of measurement

photographs has been takene befor and after treatment
using Adobe Photoshop software

Secondary outcomes

1

Description

There is no secondary outcome measure in this study,
the degree of pigmentation is the only outcome.

Timepoint

-

Method of measurement

-

Intervention groups

1

Description

Diode laser 810 nm: the 2w-810nm laser beam will be
activated using the brush technique and in contact
bmode. Application period differs according to the
degree of melanin pigmentation and epithelial thickness
of treated area.

Category

Treatment - Surgery

2

Description

Cryosurgery: The cryosurgery will be done with cotton
swab. The swab will gently touch and rol on the erea for
10_15 seconds until disappear erea of gingival
pigmentation and looks frosty

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Dental School Of Ahvaz Jundishapur University Of
Medical Sciences

Full name of responsible person

Dr. Salman Abolfazli

Street address

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz Jundishapur University Of Medical Sciences

Full name of responsible person

Dr. Salman Abolfazli

Street address

Ahvaz Jundishapur University Of Medical Sciences-
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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Ahvaz Jundishapur 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**Name of organization / entity**

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Full name of responsible person

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Position

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Web page address

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