

# 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

Elaheh Esfandiari

##### Name of organization / entity

Ahvaz Jundishapur University Of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 913 386 5262

##### Email address

esfandiari.e@ajums.ac.ir

#### 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 area 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-  
School Of Dental Medicine

**City**

Ahvaz

**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**

Ahvaz Jundishapur University Of Medical Sciences

**Full name of responsible person**

Dr Elaheh Esfandiari

**Position**

resident of periodontics

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### Person responsible for scientific inquiries

**Contact****Name of organization / entity**

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**Full name of responsible person**

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**Position**

Assistant professor

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### Person responsible for updating data

**Contact****Name of organization / entity****Full name of responsible person**

Dr Elaheh Esfandiari

**Position****Other areas of specialty/work****Street address****City****Postal code****Phone**

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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*