

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

21 Jun 2026

### Comparison of Recurrent Rate of Gingival Pigmentation after Treatment by Liquid Nitrogen and cryoprob in 18 Months Follow up in people who have anterior physiologic gingival pigmentation

#### Protocol summary

##### Summary

Objectives: Various depigmentation techniques have been employed to manage gingival pigmentation. Cryosurgery is one of the simplest, most effective depigmentation methods. Repigmentation may happen after a while. The aim of this clinical trial is to compare the recurrence rate of gingival pigmentation after treatment by cryosurgery with application of liquid nitrogen by Swap and applying cryoprob in 18 months follow up. Design: Interventional, not blinded, Unicenter, no placebo. Population: 26 patients without age limitation, no sex limitation Inclusion Criteria: physiologic gingival pigmentation were selected. Setting and conduct: The anterior sextant was divided into 2, left and right segments; each segment was treated randomly by swap technique or cryoprob. Standard photos were taken from the experimental sites, before the treatment and at 2 week, 1, 3, 6, 9, 12, 15, 18 months after the treatment. The photographs were evaluated by using color analyzing systems of RGB and CMYK with photoshop software. Exclusion criteria: Gingival pigmentation of any systemic disease. Sample Size: 52 intervention Intervention: utilization of Cryo probe and Cryo swab Intervention Duration: 18 month Primary Result: Gingival Depigmentation Secondary consequence: Gingival Pigmentation Recurrence

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013022512594N1**

Registration date: **2013-07-22, 1392/04/31**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2013-07-22, 1392/04/31

##### Registrant information

###### Name

Saba Badihi

###### Name of organization / entity

Dental School, Khorasgan Branch, Islamic Azad University

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 1234 5917

###### Email address

s.badihi@khuif.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Investigator

##### Expected recruitment start date

2011-02-04, 1389/11/15

##### Expected recruitment end date

2011-07-23, 1390/05/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of Recurrent Rate of Gingival Pigmentation after Treatment by Liquid Nitrogen and cryoprob in 18 Months Follow up in people who have anterior physiologic gingival pigmentation

##### Public title

Recurrence in Gingival Pigmentation therapy

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion Criteria physiologic melanin pigmentation of the gingiva Exclusion Criteria Gingival pigmentation of any systemic disease;Pigmentation caused by certain medications such as antimalarial drugs;anti-bacterial drug Smoking; Gingivitis; known hypersensitivity to the liquid nitrogen and N2O.

**Age**

No age limit

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

No information

**Sample size**

Target sample size: 52

**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****1****Registry name**

-

**Secondary trial Id**

-

**Registration date**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Islamic Azad University,  
Khorasgan Branch

**Street address**

Khorasgan Branch, Islamic Azad University, University  
Boulevard, Arghavaniyeh Street, Eastern Jey Street,  
Isfahan, Iran

**City**

Isfahan

**Postal code****Approval date**

2011-04-23, 1390/02/03

**Ethics committee reference number**

90021007904

**Health conditions studied****1****Description of health condition studied**

Gingival Pigmentation

**ICD-10 code**

K06.9

**ICD-10 code description**

Disorder of gingiva and edentulous alveolar ridge,  
unspecified

**Primary outcomes****1****Description**

Gingiva melanin Pigmentation rate

**Timepoint**

pretreatment, 2week, 1, 3, 6, 9, 12, 15, 18months after  
the treatment

**Method of measurement**

using color analyzing systems of RGB and CMYK with  
photoshop software

**Secondary outcomes****1****Description**

Mean of the value of Gingival Pigmentation

**Timepoint**

pretreatment, 2week, 1, 3, 6, 9, 12, 15, 18 months after  
the treatment

**Method of measurement**

color analyzing systems of RGB and CMYK with  
photoshop software

**Intervention groups****1****Description**

The anterior sextant of lower jaw was used as a control  
group (without any intervention).

**Category**

Treatment - Devices

**2****Description**

In this clinical trial Two types of cryogen were used:  
liquid nitrogen and nitrous oxide with No specific  
concentration or specific dose, that connected to the  
pigmented gingiva. The anterior sextant of upper jaw  
was divided into 2, left and right segments; each  
segment was treated randomly by swab dipped in liquid  
nitrogen and cryoprob that connected to the nitrous  
oxide cylinder. Each method was performed only once  
for each patient , and just for a few seconds.

**Category**

Treatment - Devices

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Department of Periodontology, Dental School,  
Khorasgan Branch, Islamic Azad University

##### Full name of responsible person

Saba Badihi

##### Street address

Dental School, Khorasgan Branch, Islamic Azad  
University, Arghavaniyeh Street, Eastern Jey Street,  
Isfahan, Iran

##### City

Isfahan

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice Chancellor for Research, Dental School,  
Khorasgan Branch, Islamic Azad University

##### Full name of responsible person

Dr Vahid Esfahanian

##### Street address

Dental School, Khorasgan Branch, Islamic Azad  
University, Arghavaniyeh Street, Eastern Jey Street,  
Isfahan, Iran

##### City

Isfahan

##### 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, Dental School, Khorasgan  
Branch, Islamic Azad University

##### 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

Dental School, Khorasgan Branch, Islamic Azad  
University

##### Full name of responsible person

Saba Badihi

##### Position

Dentist, DDs

##### Other areas of specialty/work

##### Street address

Dental School, Khorasgan Branch, Islamic Azad  
University, University Boulevard, Arghavanieh Street,  
Eastern Jey Street, Isfahan, Iran

##### City

Isfahan

##### Postal code

##### Phone

+98 31 1234 5917

##### Fax

##### Email

s.badihi@khuisf.ac.ir

##### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Department of Periodontology, Dental School,  
Khorasgan Branch, Islamic Azad University

##### Full name of responsible person

Shirin Amini Sedeh

##### Position

Assistant Professor/ DDs,MS

##### Other areas of specialty/work

##### Street address

Dental School, Khorasgan Branch, Islamic Azad  
University, University Boulevard, Arghavanieh Street,  
Eastern Jey Street, Isfahan, Iran

##### City

Isfahan

##### Postal code

##### Phone

+98 31 1535 4053

##### Fax

##### Email

sh.amini@khuisf.ac.ir

##### Web page address

## Person responsible for updating data

#### Contact

##### Name of organization / entity

Dental School, Khorasgan Branch, Islamic Azad  
University

##### Full name of responsible person

Saba Badihi

##### Position

Dentist, DDs

##### Other areas of specialty/work

##### Street address

Dental School, Khorasgan Branch, Islamic Azad  
University, University Boulevard, Arghavanieh Street,  
Eastern Jey Street, Isfahan, Iran

##### City

Isfahan

##### Postal code

**Phone**

+98 31 1234 5917

**Fax****Email**

s.badihi@khuisf.ac.ir

**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*