Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of gingival depigmentation by open and closed cryosurgery in an Iranian population: A clinical trial

Protocol summary

Summary

Aim: Various depigmentation techniques have been employed to manage gingival pigmentation. Cryosurgery is one of the simplest, most effective depigmentation methods. The aim of this clinical trial is to compare the reduction of gingival pigmentation after treatment by cryosurgery with application of liquid nitrogen by Swab and utilizing cryoprob in 6 months follow up. Study Design: Interventional, single blind, unicenter, randomized clinical trial. Population: Sixteen adult patients (16-50) without sex limitation with physiologic gingival pigmentation were selected. The anterior sextant was divided into left and right segments; each segment was treated randomly by open technique using swab or close method by means of cryoprob. Standard photos were taken from the experimental sites, before the treatment and at 2 weeks, 1, 3, 6 months after the treatment. The photographs were evaluated by using color analyzing systems of Red-Green-Black (RGB) and Cyan-Magenta-Yellow-Black (CMYK) with photoshop software by a professional person blind to the selected treatment technique. The intensity of pain during the treatment was compared between two groups by using a questionnaire. Exclusion criteria: Gingival pigmentation due to any systemic disease. Sample Size: Thirty-two interventions were performed in 16 individuals. Intervention: Utilization of Cryoprob and Cryo swab. Intervention Duration: 6 months. Primary Result: Gingival depigmentation. Secondary consequence: Pain during treatment and recurrence.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013091012487N3**
Registration date: **2013-10-22, 1392/07/30**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2013-10-22, 1392/07/30

Registrant information

Name
Shirin Amini
Name of organization / entity
Khorasgan Branch, Islamic Azad University, Isfahan
Country
Iran (Islamic Republic of)
Phone
+98 31 1535 4053
Email address
sh.amini@khuisf.ac.ir

Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2011-02-04, 1389/11/15

Expected recruitment end date

2011-06-13, 1390/03/23

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of gingival depigmentation by open and closed cryosurgery in an Iranian population: A clinical trial

Public title

Comparison of two Cryotherapy techniques in gums color

Purpose

Treatment

Inclusion/Exclusion criteria
Inclusion Criteria: Gingival physiologic melanin pigmentation. Exclusion Criteria: Gingival pigmentation due to any systemic diseases, pigmentation caused by certain medications such as antimalarial drugs, anti-bacterial drug, smoking, gingivitis and known hypersensitivity to the liquid nitrogen and N2O.
Age
From **15 years** old to **50 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **32**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
Randomization: Each patient was given a number from 1 to 16. The anterior sextant was divided into left and right segments from mid-line, after isolating of the location by cotton rolls, each segment was treated randomly by either swap technique or cryoprob, based on even or odd number of the patients. Blindness: All pre and postoperative photographs were traced and measured by another examiner who is expert in using photoshop software and was blind to the utilized technique in each segment.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Khorasgan Branch, Islamic Azad University
Street address
Islamic Azad University Khorasgan (Isfahan) Branch, University Boulevard, Arghavanieh, Eastern Jay Street, Isfahan, Iran.
City
Isfahan
Postal code
81595158
Approval date
2011-01-23, 1389/11/03
Ethics committee reference number
06807/890329/د

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
Gingival color
Timepoint
Pretreatment, 2weeks,1, 3 and 6 months after the treatment
Method of measurement
using color analyzing systems of RGB and CMYK with photoshop software

Secondary outcomes

1

Description
Recurrence of Pigmentation
Timepoint
2week,1,3,6 months after the treatment
Method of measurement
color analyzing systems of RGB and CMYK with photoshop software

2

Description
Pain
Timepoint
During and post operation
Method of measurement
Visual Analogue Scale by Questionnaire

Intervention groups

1

Description
Case2: Cryoprob model C505T, Danesh Company, Iran. The prob was applied to pigmented areas (4 mm in diameter) for 10-15 second. This procedure was repeated 4 or 5 times for each segment.
Category
Treatment - Devices

2

Description

Case1: Liquid Nitrogen, Iran Liquid nitrogen100% ,Zeitun Company,Iran, was applied to pigmented areas by a cotton swab (4 mm in diameter) with a forward and backward rolling technique. This procedure was repeated 4 or 5 times for each area.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Periodontology Department, Dental School, Khorasgan Branch (Isfahan), Islamic Azad University

Full name of responsible person

Street address

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

vice chancellor for research of Islamic Azad University Khorasgan Branch

Full name of responsible person

Esfahanian, Vahid

Street address

Islamic Azad University Khorasgan (Isfahan) Branch, University Boulevard, Arghavanieh, Eastern Jay 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 of Islamic Azad University Khorasgan Branch

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

Islamic Azad Dental School Khorasgan Branch, (Isfahan), Iran

Full name of responsible person

Amini, Shirin

Position

Assistant Professor/ DDS, MSc

Other areas of specialty/work

Street address

Islamic Azad University Khorasgan (Isfahan) Branch, University Boulevard, Arghavanieh, Eastern Jay Street, Isfahan, Iran.

City

Isfahan

Postal code

81595158

Phone

+98 31 1535 4053

Fax

Email

Sh.amini@khuisf.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad Dental School Khorasgan Branch, (Isfahan), Iran

Full name of responsible person

Amini, Shirin

Position

Assistant Professor/ DDS, MSc

Other areas of specialty/work

Street address

Islamic Azad University Khorasgan (Isfahan) Branch, University Boulevard, Arghavanieh, Eastern Jay Street, Isfahan, Iran

City

Isfahan

Postal code

81595158

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

Islamic Azad Dental School Khorasgan Branch, (Isfahan), Iran

Full name of responsible person

Ferdosizadeh, Fatemeh

Position

Dentist, DDs
Other areas of specialty/work
Street address
Islamic Azad University Khorasgan (Isfahan) Branch, University Boulevard, Arghavanieh, Eastern Jay Street, Isfahan, Iran
City
Isfahan
Postal code
81595158
Phone
+98 31 1535 4053
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