Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 was taken from the experimental sites, before the treatment and at 2week,1,3,6,9,12,15,18months 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

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Name of organization / entity

Dental School, Khorasgan Branch, Islamic Azad University

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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 thrapy

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

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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

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

City
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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
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

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Position
Dentist, DDs

Other areas of specialty/work

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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