

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

A Comparison of 940 nm Diode Laser and Cryosurgery with Liquid Nitrogen in the Treatment of Gingival Physiologic Hyperpigmentation using Split Mouth Technique

Protocol summary

Study aim

To determine the most effective method for gingival depigmentation among 940 nm Diode Laser Therapy and Cryosurgery with Liquid N2

Design

Randomised clinical trial with double blinded outcome assessment, split mouth design of 15 patients, between February 2016 and February 2017 and followed for one year.

Settings and conduct

The two mentioned techniques were compared in terms of gingival depigmentation, postoperative pain, healing duration, pigmentation recurrence and patients' satisfaction. Gingiva of each patient was splitted into two halves and each half randomly received one treatment modality. In this double-blinded study patients and persons examining the treatment results were unaware of the type of treatment modalities each half received. This study was conducted in Arak University of Medical Sciences. Patients were followed up to 21 days for the assessment of gingival healing and up to 12 months after the treatments to detect any sign of pigmentation recurrence.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Physiologic Gingival Hyperpigmentation
Exclusion criteria: Oral melanotic macule, Malignant melanoma, Hemochromatosis, Pigmentation due to pharmaceutical and heavy metals, Pregnancy-related pigmentation, Amalgam tattoo, Drug-induced melanosis, Smoker's melanosis, etc.

Intervention groups

The efficacy of the two therapeutic methods in gingival physiologic pigmentation were compared: Intervention group 1: 940 nm Diode laser; Intervention group 2: Cryotherapy with liquid N2

Main outcome variables

Physiologic Gingival Pigmentation Index; Post-operative

pain; Duration of Gingival Healing; Pigmentation recurrence; Patients' satisfaction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160408027277N1**

Registration date: **2018-10-06, 1397/07/14**

Registration timing: **retrospective**

Last update: **2018-10-06, 1397/07/14**

Update count: **0**

Registration date

2018-10-06, 1397/07/14

Registrant information

Name

Mohammad Keivan

Name of organization / entity

Dr. Mohammad Keivan Private Dental Clinic

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2015-03-01, 1393/12/10

Expected recruitment end date

2016-04-03, 1395/01/15

Actual recruitment start date

2016-02-29, 1394/12/10

Actual recruitment end date

2016-04-03, 1395/01/15

Trial completion date

2016-04-03, 1395/01/15

Scientific title

A Comparison of 940 nm Diode Laser and Cryosurgery with Liquid Nitrogen in the Treatment of Gingival Physiologic Hyperpigmentation using Split Mouth Technique

Public title

Laser therapy and Cryosurgery in the treatment of Gingival Physiologic Hyperpigmentation

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Physiologic Gingival Hyperpigmentation

Exclusion criteria:

Amalgam tattoo Oral melanotic macule Malignant melanoma Drug-induced melanosis Smoker's melanosis Melanosis associated with systemic and genetic diseases Hemochromatosis Graphite tattoo Decorative tattoos Pigmentation due to pharmaceutical and heavy metals Pregnancy-related pigmentation

AgeFrom **17 years** old to **35 years** old**Gender**

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample sizeTarget sample size: **15**

More than 1 sample in each individual

Number of samples in each individual: **2**

Each individual receives two types of treatments (Laser and Cryosurgery)

Actual sample size reached: **15**

More than 1 sample in each individual

Actual sample size in each individual: **2**

Each individual received two types of treatments (Laser and Cryosurgery)

Randomization (investigator's opinion)

Randomized

Randomization description

Maxillary gingiva of each patient was split into right and left halves (Split Mouth technique). One half was treated by 940 nm diode laser and the other half by cryosurgery. The divided areas were randomly allotted for depigmentation by coin toss.

Blinding (investigator's opinion)

Double blinded

Blinding description

The study is designed double blinded so that the participants in the study (patients) are unaware of the

type of intervention implemented on their gums and the experts reviewing the results of the two interventions are also unaware of the type of intervention done on the patients' gingival sites. In order to achieve the goals of blindness in this study, it needs to be explained that the expert doing the surgical procedure is different from the one evaluating the results of the two surgical procedures and the expert evaluator is completely unaware of the type of surgical method used in the surgical sites and is selected from outside of the surgical team.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Arak University of Medical Sciences

Street address

Arak University of Medical Sciences, Basij Square, Sardasht, Khalij Fars Boulevard

City

Arak

Province

Markazi

Postal code

3819693345

Approval date

2016-02-20, 1394/12/01

Ethics committee reference number

IR.ARAKMU.REC.1395.7

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

Physiologic Gingival Hyperpigmentation

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Physiologic Gingival Pigmentation Index

Timepoint

Before treatment, 3, 7, 10, 17, 21 days and 1, 3, 6, 12 months post-operatively

Method of measurement

Observation

Secondary outcomes

1

Description

Post-operative pain

Timepoint

On the day of treatment

Method of measurement

Questionnaire

2

Description

Duration of Gingival healing

Timepoint

Before treatment, 3, 7, 10, 14,17 and 21 days post-operatively

Method of measurement

Observation

3

Description

Pigmentation recurrence

Timepoint

1, 3, 6, 12 months after the treatment

Method of measurement

Observation

4

Description

Patient satisfaction

Timepoint

one year after treatment

Method of measurement

questionnaire

Intervention groups

1

Description

Intervention group 1: 940 nm Diode Laser, Epic™ 10 diode type with wavelength of 940 ± 10 nm, operating maximum power output of 10W, 0.01 ms to 20 s pulse duration, contact continuous mode, with 300 μ m fiber tip diameter, spot size 30mm diameter (= 7.1 cm² area) and manufactured by Biolase Company, USA. Firstly, gingiva received anesthesia with 2% lidocaine and the tip of laser was placed and moved on the entire pigmented area from the mucogingival line towards the free gingival margin, including the papillae until the pigmented area was de-epithelialized and a normal pink color of gingiva was apparent. The carbonized gingiva was wiped with a moist sterile gauze to ensure that no pigmented spots remained.

Category

Treatment - Devices

2

Description

Intervention group 2: Cryotherapy with liquid Nitrogen, a 10-liter three-chambered tank of liquid nitrogen (-196°C), made in China, was used. Some liquid nitrogen was poured inside a plastic cup and the tip of a cotton swab was dipped in the liquid and placed inside a small finger-like plastic and then placed on the pigmented gingiva for 3 to 5 seconds. Sessions of cryosurgery was repeated until depigmentation was satisfactory.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Arak Dental School

Full name of responsible person

Research committee of Arak University of Medical Science . Dr. Mohammad Arjmandzadegan

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Between Andisheh 5 and 6 Alleys, Ghadir Blvd., Nabaei town, Sardasht

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Arak University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr. Mohammad Keivan

Position

Dentist

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

After the publication of this article in a journal if the privacy of patients is not invaded information will be given to the respected center.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available