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 ginigval 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. I n theis 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)
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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 Hyperpigmentaion
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
Age
From **17 years** old to **35 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target 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, EpicTM 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 µm 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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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
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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