Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of efficacy of conventional laser irradiation versus a new method for depigmentation in patients with gingival pigmentation

Protocol summary

Summary

This study sought to compare the efficacy of two diode laser irradiation protocols for treatment of gingival pigmentations namely the conventional method and the sieve method. The study design was non-randomized, single blind, positive control with conventional method, uni center and 2nd phase trial. Inclusion criteria consists of patients with gingival pigmentation who seek treatment. The exclusion criteria include systemic disease and cigarette smoking. Sample size was calculated 15 patients. Intervention: Diode laser (980 nm wavelength and 2Watt power) was irradiated through a stipple pattern (sieve method) and conventionally (980 nm wavelength and 2Watt power) in the other side of the mouth by brush stroke pattern. Patients were followed at two weeks, one month and three months. For primary outcome measurement pigmentation levels were determined using Dummett's oral pigmentation index (DOPI). secondary outcome; pain, was assessed by visual analogue scale (VAS).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015111024988N1**
Registration date: **2016-03-12, 1394/12/22**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-03-12, 1394/12/22

Registrant information

Name

Noushin Janbakhsh

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 913 316 7499

Email address

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Recruitment status

Recruitment complete

Funding source

Dental School of Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2015-04-18, 1394/01/29

Expected recruitment end date

2015-07-20, 1394/04/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of efficacy of conventional laser irradiation versus a new method for depigmentation in patients with gingival pigmentation

Public title

efficacy of conventional laser irradiation versus a new method for gingival depigmentation

Purpose

Treatment

Inclusion/Exclusion criteria

1. Physiologic gingival pigmentation both at the right left sides of mandible and maxilla extending to the distal aspect of the canines. 2. Patients' demand for depigmentation./ 1. Systemic conditions, medication intake and pregnancy or nursing 2. Pigmentations linked to malignancy 3. History of previous depigmentation

treatments 4. Cigarette smoking.

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **15**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

dental school, shahid beheshti universtity of medical sciences

Street address

daneshju boulevard, Evin, Tehran

City

Tehran

Postal code

Approval date

2016-02-10, 1394/11/21

Ethics committee reference number

IR.SBMU.RIDS.REC.1394.108

Health conditions studied

1

Description of health condition studied

gingival hyperpigmentation

ICD-10 code

L81.4

ICD-10 code description

Other melanin hyperpigmentation

Primary outcomes

1

Description

gingival pigmentation intensity

Timepoint

two weeks, one month, 3 months following the end of the treatment

Method of measurement

Dummet's oral pigmentation index

Secondary outcomes

1

Description

pain

Timepoint

first week after surgery

Method of measurement

visual analogue scale

Intervention groups

1

Description

Diode laser (980 nm wavelength and 2Watt power) was irradiated through a stipple pattern (sieve method) and conventionally (980 nm wavelength and 2Watt power) in the other side of the mouth by brush stroke pattern. Patients were followed at two weeks, one month and three months.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Periodontics, Dental School, Shahid Beheshti University of Medical Sciences

Full name of responsible person

Fatemeh Khalilian

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for Research of Dental School, Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Arash Khojasteh

Street address

Daneshjou Boulevard

City

Tehran

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 Dental School, Shahid Beheshti University of Medical Sciences

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

Department of Periodontics, School of Dentistry, Shahid beheshti University of Medical Sciences

Full name of responsible person

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Post graduate student

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