

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

Comparative study of the effect of two types of diode and CO2 lasers in the treatment of gingival pigmentation (with 3 months follow-up)

Protocol summary

Study aim

Determining the most effective method of gingival depigmentation in terms of treatment outcome, patient comfort, and patient satisfaction

Design

Randomized clinical trial with single blinded outcome assessment, split mouth design of 16 patients followed for 3 months.

Settings and conduct

The two mentioned techniques were compared in terms of gingival depigmentation, postoperative pain, pigmentation recurrence and patients' satisfaction. Gingiva of each patient was splitted into two halves and each half randomly received one treatment modality. In this single-blinded study persons examining the treatment results were unaware of the type of treatment modalities each half received. This study was conducted in Isfahan University of Medical Sciences. Patients were followed up in 1st week, 1 & 3 months after operation.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients aged 18-60 years with physiological gingival pigmentation. Exclusion criteria: patients who showed hyperpigmentation due to systemic or genetic disorders or consuming drugs; patients who were smokers patients who had periodontal diseases; pregnant and feeding women.

Intervention groups

Group 1: Maxillary quadrant treated with diode laser.
Group 2: Maxillary contrast quadrant treated with CO2 laser.

Main outcome variables

Physiologic Gingival Pigmentation Index; Post-operative pain; Pigmentation recurrence; Patients' satisfaction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200309046728N1**

Registration date: **2020-04-16, 1399/01/28**

Registration timing: **registered_while_recruiting**

Last update: **2020-04-16, 1399/01/28**

Update count: **0**

Registration date

2020-04-16, 1399/01/28

Registrant information

Name

Samaneh Soltani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3669 9110

Email address

m-soltani@bsc.araku.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-21, 1398/08/30

Expected recruitment end date

2020-04-28, 1399/02/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of the effect of two types of diode and CO2 lasers in the treatment of gingival pigmentation (with 3 months follow-up)

Public title

Investigation of the effect of laser on darkening of the gums

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients 18-60 years old Systemic health Physiologic gingival pigmentation

Exclusion criteria:

Hyperpigmentation due to systemic or genetic disorders Consuming drugs cause Hyperpigmentation Smoking Patients with periodontal disease Pregnant And feeding Women

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **16**

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 diode laser and the other half by CO2 laser. The divided areas were randomly allotted for depigmentation by coin toss

Blinding (investigator's opinion)

Single blinded

Blinding description

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 evaluate 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 Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezar Jarib Ave.

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2020-04-03, 1399/01/15

Ethics committee reference number

IR.MUI.RESEARCH.REC.1399.010

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

Pigmentation area

Timepoint

0, 1 month & 3 months later

Method of measurement

with image J software

2

Description

RGB Index in Gingiva

Timepoint

0,1, 3 months later

Method of measurement

Photoshop software

Secondary outcomes

1

Description

Post operation pain

Timepoint

1 hour, 1 day & 1 week

Method of measurement

Questionnaire(Visual Analog Scale)

2

Description

Patient satisfaction
Timepoint
3 months
Method of measurement
Questionnaire

Intervention groups

1

Description

Intervention group: CO2 laser. The segments in this group underwent gingival depigmentation with CO2 laser at Super Dream Pulse and non-contact mode. the operation will be done in one session that takes about an hour.

Category

Treatment - Surgery

2

Description

Intervention group: Diode Laser. The segments in this group underwent gingival depigmentation with diode laser (980 nm) at continuous and contact mode. the operation will be done in one session that takes about an hour.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

School Of Dentistry, Isfahan University of Medical science

Full name of responsible person

Samaneh Soltani

Street address

Periodontal department, School of Dentistry, Isfahan University of Medical Sciences

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3792 5570

Email

Sas_851050@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghgoy

Street address

Isfahan University of Medical Sciences, Hezar Jirib St.

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3792 3060

Email

sh_haghjoo@med.mui.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Samaneh Soltani

Position

Resident of Periodontics

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

Street address

Periodontal department, School of Dentistry, Isfahan University of Medical Sciences

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3792 5570

Email

Sas_851050@yahoo.com

Person responsible for scientific

inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Reza Birang

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Periodontal department, School of Dentistry, Isfahan
University of Medical Sciences

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3792 5570

Email

birang@dnt.mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

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Samaneh Soltani

Position

Resident of Periodontics

Latest degree

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Postal code

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Phone

+98 31 3792 5570

Email

Sas_851050@yahoo.com

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

No more information

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