

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

A comparison of CO2 laser and different modes of diode laser in management of gingival melanin pigmentation

Protocol summary

Study aim

to compare the effectiveness of CO2 laser and pulsed versus continuous modes of diode laser for gingival depigmentation.

Design

Superiority, split-mouth group, double blind, randomized clinical trial. The randomization is performed using a computer-generated table.

Settings and conduct

The study is contemplated in Laser Department, School of Dentistry, Mashhad University of Medical Sciences, Mashhad, Iran To ensure the double-blind design of the study, neither the patient nor the subject who assesses the outcomes are aware of the group assignment.

Participants/Inclusion and exclusion criteria

12 patients with the chief complaint of dark gums

Intervention groups

The upper right and left anterior segments and the mandibular anterior segment were randomly assigned to one of the treatment groups. The segments in group 1 underwent gingival depigmentation with diode laser (810 nm) at 6 W and pulsed mode, whereas group 2 was ablated with diode laser at 3 W and continuous mode. The removal of gingival pigments in group 3 was contemplated with CO2 laser (3 W, continuous mode).

Main outcome variables

The operation chair time, gingival color

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20091118002736N4**

Registration date: **2020-02-16, 1398/11/27**

Registration timing: **retrospective**

Last update: **2020-02-16, 1398/11/27**

Update count: **0**

Registration date

2020-02-16, 1398/11/27

Registrant information

Name

Farzaneh Ahrari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 1883 1145

Email address

ahrarif@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-05, 1398/10/15

Expected recruitment end date

2020-02-05, 1398/11/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison of CO2 laser and different modes of diode laser in management of gingival melanin pigmentation

Public title

Comparison of CO2 and diode lasers in gingival pigmentation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

over 18 years old presence of bilateral physiologic

gingival pigmentation (score 2 of Melanin pigmentation index in the anterior parts of upper and lower jaws

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

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **12**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization was performed using a computer-generated table.

Blinding (investigator's opinion)

Double blinded

Blinding description

To ensure the double-blind design of the study, neither the patient nor the subject who assessed the outcomes were aware of the group assignment.

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mashhad University of Medical Sciences

Street address

Vakilabad Blvd

City

Mashhad

Province

Razavi Khorasan

Postal code

9177873476

Approval date

2016-04-12, 1395/01/24

Ethics committee reference number

IR.mums.sd.REC.1395.124

Health conditions studied

1

Description of health condition studied

bilateral physiologic gingival pigmentation

ICD-10 code

K06

ICD-10 code description

Other disorders of gingiva and edentulous alveolar ridge

Primary outcomes

1

Description

1- Operation chair time

Timepoint

during intervention

Method of measurement

seconds

2

Description

gingival color assessment

Timepoint

before treatment and after 7 days and 3 months of the surgical procedure

Method of measurement

Easyshade spectrophotometer

Secondary outcomes

1

Description

2- Bleeding:

Timepoint

during treatment

Method of measurement

observation (A. none, B. slight, C. moderate, D. Severe)

2

Description

Pain assessment

Timepoint

at 6 and 12 hours after operation and at bedtime on days 1, 3, 5 and 7 after the procedure

Method of measurement

visual analogue scale

Intervention groups

1

Description

Intervention group 1: The segments in group 1 underwent gingival depigmentation with diode laser (810 nm) at 6 W and pulsed mode

Category

Treatment - Surgery

2

Description

Intervention group 2: The patients in group 2 were ablated with diode laser at 3 W and continuous mod

Category

Treatment - Surgery

3

Description

Intervention group 3: The removal of gingival pigments in group 3 was contemplated with CO2 laser (3 W, continuous mode).

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

School of Dentistry, Mashhad University of Medical Sciences, Mashhad, Iran

Full name of responsible person

Amir Moeintaghavi

Street address

Vakilabad Blvd

City

Mashhad

Province

Razavi Khorasan

Postal code

9177873476

Phone

+98 51 3882 9502

Email

moeintaghavia@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

Daneshgah St

City

Mashhad

Province

Razavi Khorasan

Postal code

9177873477

Phone

+98 51 3841 2081

Email

Tafaghodim@mums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Farzaneh Ahrari

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Vakilabad Blvd

City

Mashhad

Province

Razavi Khorasan

Postal code

9177873476

Phone

+98 51 3882 9502

Email

Ahrarif@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Farzaneh Ahrari

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Vakilabad Blvd

City
Mashhad
Province
Razavi Khorasan
Postal code
9177873476
Phone
+98 51 3882 9502
Email
Ahrarif@mums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Farzaneh Ahrari
Position
Associate Professor
Latest degree
Specialist
Other areas of specialty/work
Dentistry
Street address
Vakilabad Blvd
City
Mashhad
Province
Razavi Khorasan

Postal code
9177873476
Phone
+98 51 3882 9502
Email
Ahrarif@mums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available