Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 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
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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
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Sponsors / Funding sources

1

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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
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
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Farzaneh Ahrari
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Associate Professor
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Specialist
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Person responsible for updating data

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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