Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Nov 2026

Comparison of Conventional and CO2 laser techniques in treatment of gingival pigmentation in adults

Protocol summary

Study aim
The aim of the present study is to compare two treatment modalities including conventional and Co2 laser methods in treatment of gingival pigmentation

Design
In this clinical trial, fifteen patients with chief complaint of physiologic gingival pigmentation are chosen. Gingival depigmentation is done via conventional method in the right half of maxillary anterior sextant, and CO2 laser in the left half of maxillary anterior sextant in a split-mouth design.

Settings and conduct
Gingival depigmentation is done using conventional and CO2 laser methods in maxillary anterior sextant in one session in a split mouth design at laser department, dental faculty.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Physiologic entity of gingival pigmentation; Medium to severe hyperpigmentation; Good plaque control. Exclusion criteria: Background reasons or environmental factors as etiology of hyperpigmentation such as endocrine disorders or smoking; Pregnancy or breast feeding; Thin biotype of periodontium; Acute gingival or periodontal disease

Intervention groups
Two treatment modalities for gingival depigmentation including conventional method and CO2 laser

Main outcome variables
Area of pigmentation

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170601034288N1**
Registration date: **2017-12-19, 1396/09/28**
Registration timing: **prospective**
Last update: **2017-12-19, 1396/09/28**
Update count: **0**

Registration date
2017-12-19, 1396/09/28

Registrant information

Name
Maryam Nourelahi

Name of organization / entity
Semnan University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 23 3334 1449

Email address
m.noorelahi@semums.ac.ir

Recruitment status
Recruitment complete

Funding source
Vice chancellor for research, Semnan University of Medical Sciences

Expected recruitment start date
2017-12-31, 1396/10/10

Expected recruitment end date
2018-12-01, 1397/09/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of Conventional and CO2 laser techniques in treatment of gingival pigmentation in adults

Public title
Comparison of Conventional and Laser techniques in treatment of gingival pigmentation in adults

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Physiologic entity of gingival pigmentation Medium to severe hyperpigmentation based on Dimmitt-Gupta index (DOP) Plaque index less than 20%

Exclusion criteria:

Medical history which affects the process of tissue healing Background or environmental factors as etiology of hyperpigmentation such as endocrine disorders or smoking Pregnancy or breast feeding Thin biotype of periodontium Acute gingival or periodontal disease

Age

From **18 years** old to **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **15**

More than 1 sample in each individual

Number of samples in each individual: **2**

Left side of maxillary anterior sextant; right side of maxillary anterior sextant

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Semnan University of Medical Sciences

Street address

Basij Blvd. Amirkabir bridge

City

Semnan

Province

Semnan

Postal code

35198-99951

Approval date

2017-05-21, 1396/02/31

Ethics committee reference number

IR.SEMUMS.REC.1396.2

Health conditions studied

1

Description of health condition studied

Gingival pigmentation

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Area of pigmentation

Timepoint

Before the procedure, 1 and 6 months after the procedure

Method of measurement

Taking standard photographs and then quantifying area of pigmentation using Gridlines option in Microsoft Paint software

Secondary outcomes

1

Description

Amount of gingival recession

Timepoint

Before the procedure, 1 and 6 months after the procedure

Method of measurement

Distance from gingival margin to Cemento Enamel Junction

Intervention groups

1

Description

Gingival depigmentation using CO2 laser in the left half of maxillary anterior sextant. In this method CO2 laser (6w, 100 palse/s) with fiber optic filaments is used. Contact mode is used in a cervical to apical direction. Care is taken not to harm tooth

Category

Treatment - Surgery

2

Description

Gingival depigmentation using conventional method in the right half of maxillary anterior sextant. In this method epithelial layer in pigmented areas is removed using diamond bur on high-speed dental headpiece under copious irrigation with saline solution

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center
Dental faculty, Semnan University of Medical Sciences

Full name of responsible person
Behnaz Roshannia

Street address
Faculty of dentistry, 17-Shahrivar Blvd.

City
Semnan

Province
Semnan

Postal code
35198-35198

Phone
+98 23 3334 1449

Email
behnaz.dent71@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Semnan University of Medical Sciences

Full name of responsible person
Dr Ali Rashidipoor

Street address
Vice chancellor for research, Headquarters of Semnan University of Medical Sciences, Basij Blvd.

City
Semnan

Province
Semnan

Postal code
35198-99951

Phone
+98 23 3344 1022

Email
rashidy-pour@semums.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Semnan 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
Semnan University of Medical Sciences

Full name of responsible person
Maryam Nourelahi

Position
Assistant professor/MDS

Latest degree
Specialist

Other areas of specialty/work
Dentistry

Street address
Department of Periodontology, Dental faculty,17-Shahrivar Blvd., Semnan University of Medical Sciences

City
Semnan

Province
Semnan

Postal code
3519899951

Phone
+98 23 3334 1449

Fax

Email
m.noorelahi@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Semnan University of Medical Sciences

Full name of responsible person
Maryam Nourelahi

Position
Assistant professor/MDS

Latest degree
Specialist

Other areas of specialty/work
Dentistry

Street address
Department of Periodontology, Faculty of dentistry, 17-Shahrivar Blvd.

City
Semnan

Province
Semnan

Postal code
3519899951

Phone
+98 23 3334 1449

Fax

Email
m.noorelahi@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Semnan University of Medical Sciences

Full name of responsible person
Maryam Nourelahi

Position
Assistant professor/MDS

Latest degree
Specialist

Other areas of specialty/work
Dentistry

Street address
Department of Periodontology, Faculty of dentistry, 17-Shahrivar Blvd.

City
Semnan

Province
Semnan

Postal code
3519899951

Phone
+98 23 3334 1449

Fax

Email
m.noorelahi@gmail.com

Web page address

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