

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 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 pulse/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.

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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 Rashidipour

**Street address**

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

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**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

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## Person responsible for scientific inquiries

### Contact

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**Full name of responsible person**

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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