Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of treatment outcomes of Diode 808 nm and Er,Cr:YSGG laser on physiologic gingival pigmentation

Protocol summary

Summary

The Goal of this study is comparison of treatment outcomes of Diode 808 nm and Er,Cr:YSGG laser on physiologic gingival pigmentation. Study design is interventional (Randomized clinical trial). The study population are patients with chief complaint of gingival pigmentation that present in oral medicine clinic of Shahid Beheshti University of medical sciences Dental School. Inclusion criteria: Having physiologic gingival melanin pigmentation ; Coordination of gingival pigmentation pattern in terms of intensity and extension of gingival color in left and right ; Voluntary participation in study Exclusion criteria: History of Diabetes or autoimmune disease ; Under treatment with drugs that influence on gingival color ; Pregnant or breast-feeding women ; Evidence about relation of pigmentation with malignancies ; History of previous treatment of gingival pigmentation ; Smoking ; Periodontal disease ; Uncoordination of gingival pigmentation pattern terms of intensity and extension of gingival color in left and right side. Sample size is 14 patient. Mouth divided to two parts (left and right) from midline to premolars. Randomly use in a half Er,Cr:YSGG laser and in other half Diode(808nm) laser . Er,Cr:YSGG laser in three session and Diode(808nm) laser in two session ablated. Treatment outcomes followed to 1,3 and 6 months . primary outcome is reduction of extension and intensity color of gingival pigmentation.

General information

Acronym

Gingival Melanin Depigmentation - GMD

IRCT registration information

IRCT registration number: **IRCT2015121925610N1**
Registration date: **2016-04-13, 1395/01/25**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2016-04-13, 1395/01/25

Registrant information

Name

Somayeh Rahmani

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2217 5351

Email address

s_rahmani@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Research assistant,Dentistry School,Shahid Beheshti University of Medical Scienses

Expected recruitment start date

2015-01-21, 1393/11/01

Expected recruitment end date

2016-01-21, 1394/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of treatment outcomes of Diode 808 nm and Er,Cr:YSGG laser on physiologic gingival pigmentation

Public title

effect of Diode and Erbium laser on dark gingival color

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Having physiologic gingival melanin pigmentation;Coordination of gingival pigmentation pattern in left and right side , pigmentation intensity in range of moderate to severe and maximum one score difference in extension of pigmentation; Voluntary participation in study Exclusion criteria: History of Diabetes or autoimmune disease;Under treatment with drugs that influence on gingival color; Pregnant or breast-feeding women;Evidence about relation of pigmentation with malignancies;History of previous treatment of gingival pigmentation; Smoking;Periodontal disease;Uncoordination of gingival pigmentation pattern in left and right side

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **14**

Randomization (investigator's opinion)

N/A

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

Shahid Beheshti University Of Medical Sciences - Dentistry School

Street address

Dentistry School - Daneshjoo Boulevard - Shahid Chamran High way - Tehran

City

Tehran

Postal code

1983963113

Approval date

2016-03-07, 1394/12/17

Ethics committee reference number

IR.SBMU.RIDS.REC.1394.177

Health conditions studied

1

Description of health condition studied

Physiologic Gingival Melanin Hyperpigmentation

ICD-10 code

L81.4

ICD-10 code description

Other melanin hyperpigmentation

Primary outcomes

1

Description

Intensity of pigmentation

Timepoint

Before intervention - 1 months after intervention - 3 months after intervention - 6 months after intervention

Method of measurement

Dummett–Gupta Oral Pigmentation Index (DOPI; Dummett 1971) : 1. No clinical pigmentation (pink gingiva) 2. Mild clinical pigmentation (mild light brown color) 3. Moderate clinical pigmentation (medium brown or mixed pink and brown) 4. Heavy clinical pigmentation (deep brown or bluish black)

2

Description

Extension of Pigmentation

Timepoint

Before intervention - 1 months after intervention - 3 months after intervention - 6 months after intervention

Method of measurement

– Hedin melanin index scored as follows: 0- No pigmentation 1- One or two solitary units of pigmentation in the papillary gingiva 2- >3 units of pigmentation in the papillary gingiva without formation of a continuous ribbon 3- One short continuous ribbons of pigmentation 4- One c ontinuous ribbon including the entire area between the canines

Secondary outcomes

1

Description

Pain

Timepoint

During first 24 hours after intervention

Method of measurement

Question: Visual Analogue Scale Score 0 = no pain Score1 = 1 to 30 mm = slight pain Score2= 31 to 60 mm = moderate pain Score3= 61 to 100 mm= sever pain

2

Description

Bleeding

Timepoint

During intervention

Method of measurement

inspection: with bleeding - without bleeding

3

Description

Gingival Recision

Timepoint

1 months after intervention - 3 months after intervention - 6 months after intervention

Method of measurement

inspection: with recision - without recision

4

Description

Gingival Healing

Timepoint

one week after first intervention

Method of measurement

inspection: with healing - without healing

Intervention groups

1

Description

treatment of physiologic gingival pigmentation in one quadrant of one jaw with Diode laser 808nm - 1 watt - CW

Category

Treatment - Devices

2

Description

treatment of physiologic gingival pigmentation in one quadrant of one jaw with Er,Cr:YSGG laser 2780nm- 1.75 watt - 10 % water - 20% Air- 20 HZ- Type MZ8

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti university of medical sciences - Dentistry school - Oral Medicine Departement

Full name of responsible person

Dr Mahin Bakhshi

Street address

oral Medicine Department- Dentistry school - Daneshjoo Boulevard- Evin- shahid chamran highway- Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences - Dentistry school- Research assistant

Full name of responsible person

Mohammad Reza Safavi

Street address

Dentistry school- daneshjoo boulevard - shahid chamran highway- Tehran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti University of Medical Sciences - Dentistry school- Research assistant

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences - Dentistry school

Full name of responsible person

Somayeh Rahmani

Position

Post Graduate dentistry - Oral Medicine student of Shahid Beheshti University of Medical sciences -

Other areas of specialty/work

Street address

Dentistry school - Daneshjoo Boulevard - Shahid Chamran High way- Tehran

City

Tehran

Postal code

1983963113

Phone

+98 21 2240 3075

Fax

Email

mahinbakhshi@sbmu.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Oral Medicine Department , Shahid Beheshti university of Medical Sciences-Dentistry School

Full name of responsible person
Mahin Bakhshi

Position
Oral Medicine Specialist , Associate and faculty member of Shahid Beheshti University of Medical Sci

Other areas of specialty/work

Street address
Dentistry School, Daneshjoo Boulevard, Evin,Shahid Chamran High Way,Tehran

City
Tehran

Postal code
1983963113

Phone
+98 21 2240 3075

Fax

Email
Mahinbakhshi@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences - Dnetistry School

Full name of responsible person
Somayeh Rahmani

Position
Post Gradated Dentistry - Oral Medicine Student

Other areas of specialty/work

Street address
Dentistry School - Daneshjoo Boulevard - Evin - Shahid Chamran High way- Tehran

City
Tehran

Postal code
1983963113

Phone
+98 21 2240 3075

Fax
+98 22403194

Email
s.rahmani2011@yahoo.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty