

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 May 2026

Clinical Trial of Comparison of Er,Cr:YSGG laser and surgical stripping on pain , patients satisfaction and wound healing in patients with gingival physiologic pigmentation

Protocol summary

Summary

There is an increase in tendency of esthetic removal of gingival melanin hyperpigmentation. In this randomized split mouth study we compared the standard method of removal with a blade with two different settings of the Er,Cr:YSGG laser in order to find the best treatment method. in 33 dental arches of 20 patients (13 needed treatment in both arches and 7 only in the maxilla) The three treatment groups were: surgical stripping, removal with laser setting 1 (4.5 w , 50 Hz, H mode, 80% air, 100% water)and laser setting 2 (2.5 w, S mode, 50 Hz, ,40% air, 20% water) Pain, patient satisfaction and wound healing, Treatment time and the amount of bleeding were evaluated. Re-pigmentation was recorded after one month.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016113018493N3**

Registration date: **2017-05-27, 1396/03/06**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-05-27, 1396/03/06

Registrant information

Name

Leila Gholami

Name of organization / entity

Hamadan University of Medical Sciences, Faculty of Dentistry

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research Zahedan University of Medical Sciences

Expected recruitment start date

2015-04-30, 1394/02/10

Expected recruitment end date

2015-09-01, 1394/06/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical Trial of Comparison of Er,Cr:YSGG laser and surgical stripping on pain , patients satisfaction and wound healing in patients with gingival physiologic pigmentation

Public title

the effect of laser on gum color

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: over 18 years of age; non smoker; systemically healthy individual with a healthy periodontal tissues without periodontal pockets; Loe's Gingival index of 1 or less; Dummet index of 2 or 3; Heidin index of 3 or 4 Exclusion criteria: pregnant or breastfeeding patients; being under orthodontic treatment; plaque index of more than 20%

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **33**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

The study was randomized by Block design

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Zahedan University of Medical Science

Street address

Zahedan University of Medical Science-Dr.Hesabi square Zahedan

City

Zahedan

Postal code

Approval date

2015-04-07, 1394/01/18

Ethics committee reference number

IR.Zaums.REC.1394.18.1

Health conditions studied

1

Description of health condition studied

physiologic gingival pigmentation

ICD-10 code

-

ICD-10 code description

-

Primary outcomes

1

Description

Pain

Timepoint

Immediately after treatment, 1 day and 7 days after treatment

Method of measurement

Visual analog scale of 1 to10

2

Description

Gingival wound healing

Timepoint

1 , 3 ,7 and 30 days after treatment

Method of measurement

healing score: : 0= tissue necrosis 1= ulcer formation 2= incomplete epithelialization 3= complete epithelialization

3

Description

Patient satisfaction

Timepoint

1, 7 days after treatment

Method of measurement

questionnaire

Secondary outcomes

1

Description

Treatment Procedure time

Timepoint

during treatment

Method of measurement

stop watch(in seconds)

2

Description

Bleeding during treatment

Timepoint

during treatment

Method of measurement

scale:1: None, 2: Slight, 3: Moderate, 4: Severe

3

Description

Melanin repigmentation

Timepoint

1 month

Method of measurement

Melanin Pigmentation indexes of Dummet 0= No clinical pigmentation (pink-colored gingiva), 1= Mild clinical pigmentation (mild light brown color) , 2= Moderate clinical pigmentation (medium brown or mixed pink and brown color) , 3= Heavy clinical pigmentation (deep brown or bluish black color)and Hedin: 0= No pigmentation, 1= One or two solitary unit(s) of

pigmentation in papillary gingiva without the formation of a continuous ribbon between solitary units

Intervention groups

1

Description

Intervention group 1: laser group with 50 Hz, 4.5 Watt, H mode, 100% water, 80% air

Category

Treatment - Devices

2

Description

Intervention group 2: Laser group with 50 Hertz, 2.5 Watt, S mode, 20% water, 40% air

Category

Treatment - Devices

3

Description

control group: Surgical stripping treatment

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Zahedan Faculty of Dentistry

Full name of responsible person

Zohreh molaeimanesh

Street address

Mehr street, Faculty of Dentistry

City

Zahedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Zahedan University of Medical Sciences

Full name of responsible person

Dr.Rafiq doost

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Zahedan University of Medical Sciences-Dr.Hesabi square Zahedan

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Zahedan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor

organization/entity?

Yes

Title of funding source

Vice chancellor for research, Zahedan University of Medical Sciences

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

Assistant professor, Hamedan University of medical sciences

Full name of responsible person

Leila Gholami

Position

Assistant Professor \PhD

Other areas of specialty/work

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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