Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of pulsed and continuous mode of CO2 laser in oral soft tissue surgeries

Protocol summary

Study aim

Determining the clinical success rate of CO2 lasers in both continuous and pulsed modes in patients requiring oral soft tissue surgeries

Design

Clinical trial with two groups under continuous laser and pulsed laser, with parallel groups, double-blind, randomized, phase 2 on 20 patients. Randomization is done manually.

Settings and conduct

20 patients candidated for oral soft tissue surgery were included in the study were easily and conveniently divided into two groups of 10 patients .The duration of surgery will be measured by a stopwatch. Bleeding during surgery will be recorded. Postoperative complications such as bleeding and hematoma will also be recorded in a checklist. The patient's pain will be measured using the VAS scale. Scar formation is also determined by visual examination and observation of hard, dark scar tissue after one month, and the patient's satisfaction or dissatisfaction is recorded .The present study is conducted in a double-blind manner, meaning that the pain assessor does not know which patients in each group are receiving continuous and pulsed CO2 laser. Also the patients will not be aware. It is not known which laser approach was used on them. A third person will keep the codes for each group and then give them to the data analyst.

Participants/Inclusion and exclusion criteria

Patients with oral soft tissue lesions are candidates for surgical excision of the lesion ; Age over 18 years

Intervention groups

In the continuous laser group, CW mode and 5 watts of power will be used (Ultera Dream Pulse V South Korea). In the pulsed laser group, CF mode with 248 watts of power, 50 Hz of frequency, 250 microseconds of pulse duration and 62 millijoules of pulse energy will be used.

Main outcome variables

The results of this study can be used to select the most appropriate CO2 laser method in patients undergoing oral soft tissue surgery and minimize its complications.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180224038840N5**
Registration date: **2026-01-03, 1404/10/13**
Registration timing: **prospective**

Last update: **2026-01-03, 1404/10/13**
Update count: **0**

Registration date

2026-01-03, 1404/10/13

Registrant information

Name

Seyyed Amir Seyyedi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 3322 4288

Email address

seyedi.a@umsu.ac.ir

Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-01-10, 1404/10/20

Expected recruitment end date

2027-01-10, 1405/10/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of pulsed and continuous mode of CO2 laser in oral soft tissue surgeries

Public title
Comparison of pulsed and continuous mode of CO2 laser in oral soft tissue surgeries

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with oral soft tissue lesions are candidates for surgical excision of the lesion Age over 18 years old

Exclusion criteria:
Age under 18 years old Pregnant women Immunocompromised people

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **20**

Randomization (investigator's opinion)
Randomized

Randomization description
Each participant is assigned a code, and a person outside the study, without prior knowledge, randomly assigns these codes to the continuous and pulsed CO2 laser treatment groups.

Blinding (investigator's opinion)
Double blinded

Blinding description
The present study is conducted in a double-blind manner, meaning that the pain assessor does not know which patients in each group are receiving continuous and pulsed CO2 laser treatment, and on the other hand, the patients will not be aware of these conditions and will not know which laser approach was used on them. Only a third person will keep the codes of each group and then deliver them to the data analyst.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Urmia University of Medical Sciences

Street address
Resaalat ave

City
Urmia

Province
West Azarbaijan

Postal code
5714783734

Approval date
2025-08-27, 1404/06/05

Ethics committee reference number
IR.UMSU.REC.1404.209

Health conditions studied

1

Description of health condition studied
oral soft tissue surgeries

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Duration of surgery in seconds

Timepoint
The duration of the surgery will be measured by measuring the time between the start of the surgical procedure and its completion.

Method of measurement
Using a stopwatch

2

Description
Bleeding during surgery

Timepoint
During surgery

Method of measurement
By observation and by presence or absence

3

Description
Postoperative complications

Timepoint
The presence or absence of post-surgical complications such as bleeding and hematoma will be recorded in the checklist.

Method of measurement
By observation and by presence or absence

4

Description
Postoperative scar
Timepoint
After one month
Method of measurement
By observation and by presence or absence

5

Description
Postoperative pain
Timepoint
The patient's pain will be measured approximately 4 hours after surgery and 24 hours after surgery and at a fixed time every day for a week
Method of measurement
Using VAS scale

6

Description
Patient's satisfaction
Timepoint
The patient's satisfaction or dissatisfaction will be recorded after one month.
Method of measurement
Satisfaction or dissatisfaction will be recorded using a questionnaire.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Under treatment with pulsed CO2 laser. In the pulsed laser group, CF mode with a power of 248, frequency of 50 Hz, pulse duration of 250 microseconds, and pulse energy of 62 millijoules will be used.
Category
Treatment - Devices

2

Description
Control group: will be treated with continuous wave CO2 laser with a wavelength of 10600 nm. In the continuous wave laser group, CW mode and 5 watts power will be used with CO2 laser (Ultera Dream Pulse V South Korea).
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Urmia dental faculty
Full name of responsible person
Seyyed Amir Seyyedi
Street address
Urmia Dental Faculty , Mohtasham Ave, Molavi 2 Ave, Behdari town
City
Urmia
Province
West Azarbaijan
Postal code
5714783734
Phone
+98 44 3360 7284
Email
seyedi.a@umsu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Dr Saber Qolizadeh
Street address
Urmia University of Medical Sciences , Resaalaet Ave
City
Urmia
Province
West Azarbaijan
Postal code
5714783734
Phone
+98 44 3223 7082
Email
saber@umsu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Oroumia 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

Oroumia University of Medical Sciences

Full name of responsible person
Seyyed Amir Seyyedi

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Dentistry

Street address
Urmia Dental Faculty , Mohtasham Ave, Molavi 2 Ave, Behdari town

City
Urmia

Province
West Azarbaijan

Postal code
5714783734

Phone
0098443360728

Email
Seyyediamir@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Oroumia University of Medical Sciences

Full name of responsible person
Seyyed Amir Seyyedi

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Dentistry

Street address
Urmia Dental Faculty , Mohtasham Ave, Molavi 2 Ave, Behdari town

City
Urmia

Province
West Azarbaijan

Postal code
5714783734

Phone
0098443360728

Email
Seyyediamir@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Oroumia University of Medical Sciences

Full name of responsible person
Seyyed Amir Seyyedi

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Dentistry

Street address
Urmia Dental Faculty , Mohtasham Ave, Molavi 2 Ave, Behdari town

City
Urmia

Province
West Azarbaijan

Postal code
5714783734

Phone
0098443360728

Email
Seyyediamir@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
a

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available