Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of the clinical effect of 915nm diode laser vs conventional surgery in excision of Benign exophytic of oral soft tissue lesions

Protocol summary

Study aim
Comparison of efect of laser vs surgery pain of patients
Design
All patients that come to oral medicine department of shahed dental school in 44 patients 22 patients do surgery by laser and other group do by surgey by blade and the sheed put in pocket and the randome pick by thesis advisor that dont any rule in the process and do by excell software
Settings and conduct
All patients that come to oral medicine department of shahed dental school,that have exophytic oral soft tissue that should be removal and we will fo by laser diod and surgery by blade
Participants/Inclusion and exclusion criteria
If patient not accept side effects,or patient accepts side effects
Intervention groups
All patients with minimum 18 years old that have exophytic oral soft tissue that need to be removal in 2 group first will remove by laser diode and second do by surgey by blade for comparison of pain of patient asd healing on surgical site
Main outcome variables
Comparison of pain,healing and patient comfortable

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20260718070248N1**
Registration date: **2026-09-01, 1405/06/10**
Registration timing: **prospective**

Last update: **2026-09-01, 1405/06/10**
Update count: **0**
Registration date
2026-09-01, 1405/06/10

Registrant information
Name
Seyed saman Khademi
Name of organization / entity
Shahed dental school
Country
Iran (Islamic Republic of)
Phone
+98 21 7768 5291
Email address
samankhademi1999@gmail.com

Recruitment status
Not yet recruiting
Funding source

Expected recruitment start date
2026-11-20, 1405/08/29
Expected recruitment end date
2027-01-18, 1405/10/28
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the clinical effect of 915nm diode laser vs conventional surgery in excision of Benign exophytic of oral soft tissue lesions

Public title
Comparsion of laser vs surgery in removal of oral exophytic bening soft tissue
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age above 18 years old Patient dont have uncontrolled

systemic disease Patient have exophytic orql soft tissue that should be surgery

Exclusion criteria:

Failure to attend follow-up appointments Fear of laser surgery

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

This study will be conducted as a randomized controlled trial (RCT) with a parallel-group design. The study population will be randomly divided into two groups: the first group will be treated with a 915 nm diode laser, and the second group will undergo traditional surgery. Participant allocation will be performed using a blocked randomization method (block size of 4) via Excel software, carried out by a statistical consultant who is not involved in the operational procedures.

Blinding (investigator's opinion)

Single blinded

Blinding description

Outcome assessors are blinded to the treatment allocation. Patients and the investigator administering the intervention are not blinded due to the obvious differences between laser and conventional surgical procedures. Randomization is performed using sealed opaque envelopes prepared by an independent statistician who is not involved in the study.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

School of Medicine – Shahed University (Research Ethics Committee)

Street address

Tehran, at the beginning of the Tehran-Qom Highway, opposite the Holy Shrine of Imam Khomeini.

City

Tehran

Province

Tehran

Postal code

3319118651

Approval date

2026-06-14, 1405/03/24

Ethics committee reference number

IR.SHAHED.MED.REC.1405.032

Health conditions studied

1

Description of health condition studied

Exophytic benign oral soft tissue

ICD-10 code

Y69

ICD-10 code description

Unspecified misadventure during surgical and medical care

Primary outcomes

1

Description

Pain

Timepoint

Day of surgery recall after 1week and 2week

Method of measurement

VAS chart

Secondary outcomes

empty

Intervention groups

1

Description

First group under surgery by laser diod laser 915 in laser room of shahed dental school

Category

Treatment - Surgery

2

Description

Secound group do surgery by traditional surgery by blade no15 and suture in surgery room

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahed Dental School

Full name of responsible person

Seyed Saman Khademi
Street address
Italya Alley Shahed Dental School
City
Tehran
Province
Tehran
Postal code
1417755351
Phone
+98 21 8895 9210
Email
Samankhademi1999@gmail.com
Web page address
https://dent.shahed.ac.ir/special-specialized-clinic/contact/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahed University
Full name of responsible person
Dr.Masoud.Sajedi
Street address
Italia Alley Shahed Dental School
City
Tehran
Province
Tehran
Postal code
1417755351
Phone
+98 21 8895 6227
Email
Masoudsajedi@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Professor's Research Grant
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
Shahed University
Full name of responsible person
Dr.Farid.Abbasi
Position
Head of department of oral medicine
Latest degree
Specialist
Other areas of specialty/work
Dentistry
Street address
Italia Alley Shahed Dental School
City
Tehran
Province
Tehran
Postal code
1417755351
Phone
+98 21 8895 9210
Email
Abasi110@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahed University
Full name of responsible person
Dr.Farid.Abbasi
Position
Associated professor
Latest degree
Specialist
Other areas of specialty/work
Dentistry
Street address
Italia Alley Shahed Dental School
City
Tehran
Province
Tehran
Postal code
1417755351
Phone
+98 21 8895 6227
Email
Abasi110@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Shahed University
Full name of responsible person
Dr.Seyed Saman Khademi
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Dentistry
Street address

Italia Alley Shahed Dental School

City

Tehran

Province

Tehran

Postal code

1417755351

Phone

+98 21 8895 9210

Email

Samankhademi1999@gmail.com

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

Not applicable

Data Dictionary

Not applicable