Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Evaluation of Postsurgical Wound Healing, Pain and Complications of Plasma Pen-Assisted Surgery of Reactive Exophytic Oral Soft Tissue Lesions Compared to Conventional Surgery: A Randomized Clinical Trial

Protocol summary

Study aim
To evaluate the efficacy and safety of plasma pen assisted minor oral surgery comarared to conventional minor oral surgery for the treatment of reactive exophytic soft tissue lesions

Design
Two arm parallel group, non-blinded randomised clinical trial on 30 patients. Randomized computer number generator will be used.

Settings and conduct
The subjects will be selected from patients visiting the Oral Medicine Department of Shiraz University of Medical Sciences. After baseline examination,the lesions will be completely excised using a plasma pen or surgical blade according to the standard oral surgical procedures. After retracting the basal part of the lesion superiorly using a clamp, excision will be performed such that the borders were in the intact tissue. It is important to note that the wounds made after the excision with plasma pen will be allowed for secondary healing. In contrast, wounds made with surgical blade will be closed primarily by suture after bleeding is controlled. Thereafter, the patients will be instructed to rinse the mouth with chlorhexidine ۰.۲% once a day for one week. The use of acetaminophen (۵۰۰ mg every ۶ hours) will be considered only if the patient have pain within the first ۲۴ hours after surgery.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: 1.subjects aged ۱۸ years or older 2.subjects diagnosed with reactive exophytic oral soft tissue lesions (less than one centimeter) on the buccal mucosa 3.subjects who are willing to participate in this study Exclusion Criteria: 1.Any subject diagnosed clinically with possible neoplastic changes 2.Any subject diagnosed with systemic diseases that could interfere with wound healing

Intervention groups
Control Side: Lesion excision using a plasma pen
Intervention group:Lesion excision using a surgical blade

Main outcome variables
Pain Level; Wound Healing; Complications

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20231213060357N2**
Registration date: **2025-04-11, 1404/01/22**
Registration timing: **prospective**

Last update: **2025-04-11, 1404/01/22**
Update count: **0**

Registration date
2025-04-11, 1404/01/22

Registrant information

Name
Asma Sookhakian

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-04-21, 1404/02/01

Expected recruitment end date
2025-09-22, 1404/06/31

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of Postsurgical Wound Healing, Pain and Complications of Plasma Pen-Assisted Surgery of Reactive Exophytic Oral Soft Tissue Lesions Compared to Conventional Surgery: A Randomized Clinical Trial

Public title
Evaluation of Postsurgical Wound Healing, Pain and Complications of Plasma Pen-Assisted Surgery of Reactive Exophytic Oral Soft Tissue Lesions
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
subjects (both males and females) aged ۱۸ years or older Subjects diagnosed with reactive exophytic oral soft tissue lesions (less than one centimeter) on the buccal mucosa based on the clinical findings Subjects who are willing to participate and complete this study
Exclusion criteria:
Any subject diagnosed clinically with possible neoplastic changes such as rapid growth pattern and induration Any subject diagnosed with systemic diseases that could interfere with wound healing such as diabetes
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
The random allocation will be performed using a computer random number generator. For example, a random number (e.g., ۰ or ۱) will be generated. If the random number is ۰, the participant will be assigned to the control group ; if the random number is ۱, the participant will be assigned to the intervention group.
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
Research Ethics Committee of School of Dentistry-Shiraz University of Medical Sciences
Street address
Shiraz University of Medical Science, Zand street
City
Shiraz
Province
Fars
Postal code
71348-14336
Approval date
2025-02-26, 1403/12/08
Ethics committee reference number
IR.SUMS.DENTAL.REC.1404.007

Health conditions studied

1

Description of health condition studied
Reactive Exophytic Oral Soft Tissue Lesions
ICD-10 code
D10
ICD-10 code description
Benign neoplasm of mouth and pharynx

Primary outcomes

1

Description
Pain Level
Timepoint
24 hours after the surgery, and again after 2, 3, 4, 5, 6, and 7 days
Method of measurement
Visual Analogue Scale

2

Description
Wound Healing
Timepoint
On days 7, 14, 28, and 84 after surgery
Method of measurement
Wound healing index described by Landry et al, which evaluate parameters such as presence of bleeding, supporation, granulation tissue, tissue color, and epithelialization

3

Description
Complications
Timepoint
On days 7, 14, 28, and 84 after surgery

Method of measurement
Visual inspection to examine the surgery site for any visible changes such as redness, swelling, discoloration, scar, or recurrence, and palpation to assess for any palpable abnormalities

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: After baseline examination and obtaining an informed consent, the lesions will be completely excised under local anesthesia using ۲% lidocaine with ۱:۱۰,۰۰۰ epinephrine using a plasma pen under perfectly aseptic conditions. Excision will be performed according to the standard oral surgical procedures. After retracting the basal part of the lesion superiorly using a clamp, excision will be performed such that the borders were in the intact tissue. It is important to note that the wounds occurred after the excisions with plasma pen will be allowed for secondary healing.
Category
Treatment - Surgery

2

Description
Control group: After baseline examination and obtaining an informed consent, the lesions will be completely excised under local anesthesia using ۲% lidocaine with ۱:۱۰,۰۰۰ epinephrine using a surgical blade under perfectly aseptic conditions. Excision will be performed according to the standard oral surgical procedures. After retracting the basal part of the lesion superiorly using a clamp, excision will be performed such that the borders were in the intact tissue.The incision will be closed by suture after bleeding has been controlled.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Oral and Maxillofacial Medicine Department, Shiraz School of Dentistry
Full name of responsible person
Asma Sookhakian
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Sponsors / Funding sources

1

Sponsor
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Asma Sookhakian
Position
Postgraduate Student of Oral and Maxillofacial Medicine
Latest degree
Medical doctor
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Data can be shared after de-identifying individuals.
When the data will become available and for how long
Data will be available up to 6 months after publication.
To whom data/document is available
The researchers in academic and scientific institutions
Under which criteria data/document could be used
Data will be available after the trial is completed and results are published. This data can be used for research or educational purposes upon request, with a clear description of the intended use, and subject to approval by the study team and adherence to ethical research standards.
From where data/document is obtainable
The data supporting the findings of this study will be available upon reasonable request from the corresponding author.
What processes are involved for a request to access data/document
The researchers in academic and scientific institutions can email the corresponding author and request for information.
Comments