Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of the hypnosis and lidocaine effect on accelerating wound healing in oral soft tissue ulcers due to the biopsy

Protocol summary

Study aim
Evaluating the effect of hypnosis in accelerating wound healing due to oral soft tissue biopsy.

Design
A clinical trial with a control group, with parallel groups, single-blinded, Randomized, Phase 4 on 44 patients; Binary block randomization method was used to do random allocation.

Settings and conduct
This research was conducted in 2016-2019 in the Department of Oral and Maxillofacial Medicine of the Faculty of Dentistry, Mashhad University of Medical Sciences.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Oral soft tissue lesions including ulcers, red-white, pigmented, exophytic lesions requiring biopsy؛ Lesions that were indicative of incisional or excisional biopsy. Exclusion criteria: using drugs that delay wound healing such as taking steroids, etc.; Other oral mucosal lesions except for the lesion that needs a biopsy؛ Malignancies; if the patient is not hypnotizable; Past history of psychosis, severe depression or personality disorders

Intervention groups
Intervention Group: Using the Hypnosis Method; in this group, local anesthesia does not be used. Control group: Use of local lidocaine anesthesia without Hypnosis method. Both methods do not use any material to speed wound healing.

Main outcome variables
PHI: Percentage of the healing index: Wound healing index; PUI: Percentage of the unhealed index: Wound unhealed index; T: ulcer size

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180221038808N1**
Registration date: **2020-07-10, 1399/04/20**
Registration timing: **retrospective**

Last update: **2020-07-10, 1399/04/20**
Update count: **0**

Registration date
2020-07-10, 1399/04/20

Registrant information

Name
Rosa Mostafavi Tabatabaee

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-03-10, 1395/12/20

Expected recruitment end date
2019-03-11, 1397/12/20

Actual recruitment start date
2017-03-10, 1395/12/20

Actual recruitment end date
2019-04-10, 1398/01/21

Trial completion date
2019-06-11, 1398/03/21

Scientific title
Comparison of the hypnosis and lidocaine effect on accelerating wound healing in oral soft tissue ulcers due to the biopsy

Public title

Evaluation of the hypnosis effect on accelerating wound healing in oral soft tissue ulcers due to the biopsy.

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Soft soft tissue lesions include ulcers, reddish white, pigmented, exophytic, requiring biopsy. Lesions need incisional or excisional biopsy.

Exclusion criteria:

Bad oral hygiene (through a clinical examination) Having uncontrolled systemic diseases that causes immune system or surgical interference. Uncontrolled Diabetes, Cushing's disease, or homeostasis problems Taking medications that delay wound healing (such as taking steroids, etc.) Having a psychological illness (mental illness) Cigarette smoking and alcohol and narcotics Having other oral mucosal diseases (except for a lesion that needs biopsy) Malignancies (based on histopathologic diagnosis - clinical suspicion - hematologic malignancies) Lack of proper patient hypnosis Contraindications to hypnosis and speech or dialect barriers that reject hypnosis interventions Previous psychosis - severe depression - personality disorders Previous hypnosis experience

Age

No age limit

Gender

Both

Phase

4

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **30**

Actual sample size reached: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients are randomly divided into two groups by using the binary blocks method. In this way, the fate of the two patients is determined simultaneously by random coding. For example, we obtained the following random numbers by using a calculator: 8878557034021960 To create a randomization method and the acquisition of binary blocks, we determined that if the code was 0 to 4, it would be AB, and if it was 5 to 10, it would be BA. A is the usual method, and B is a hypnosis method. By entering the first and second patient and the choice of the code 8, 8 is between 5 and 10, and BA is the B type of hypnosis, and the next is placed in the usual group, and the next number for the third and fourth patient, and so on.

Blinding (investigator's opinion)

Single blinded

Blinding description

Blinding method: This study is single-blind. The evaluator had no knowledge about the photographic of patients either in hypnosis group or in the usual group which uses local anesthesia, and the procedure was performed to give each photograph a code, and the evaluator randomly assigned the edges of the ulcers without being aware of the type of hypnosis or routine surgical procedure (usual group) and then by using Photoshop software the number of pixels per ulcer was determined in the photograph.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Dental Faculty; Mashhad University of Medical Sciences; in front of Mellat park; at the beginning of Vakilabad boulevard

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948959

Approval date

2017-06-21, 1396/03/31

Ethics committee reference number

IR.MUMS.SD.REC.1394.245

Health conditions studied

1

Description of health condition studied

Accelerating of Wound Healing due to Oral Biopsy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

PHI: Percentage of the healing index: Wound healing index: PHI = 100-PUI

Timepoint

7 days for acceleration of wound healing

Method of measurement

dentistry Endometer - Photoshop software detects the number of pixels in each ulcer's area.PHI=100- PUI

2

Description
PUI: Percentage of the unhealed index: Wound unhealed index: PUI= (T1 / T0) * 100
Timepoint
7 days for unhealed index
Method of measurement
PUI= (T1/ T0) *100

3

Description
T: ulcer size
Timepoint
On the day of biopsy (post-cut)- Seven days after the biopsy (Suture thread opening day)
Method of measurement
Endometer - Determining the number of pixels on Photoshop

Secondary outcomes

1

Description
Pain
Timepoint
Pain the day before the biopsy- pain on the day of biopsy- pain one day after the biopsy- pain two days after the biopsy
Method of measurement
Visual Analog Scale

2

Description
Anxiety
Timepoint
Preoperative- During surgery
Method of measurement
Beck’s questionaries

Intervention groups

1

Description
Intervention group: Using hypnosis: Performing hypnosis in the intervention group using the naturalistic technique performed by the hypnotherapist. In hypnosis, after deepening, hypnosis analgesia with the Dissociation approach (subjective of place and time), if necessary, using indirect inductions. At the same time, the patient was conditioned to reduce postoperative pain and increase post-operative wound healing rate after surgery. Conditioning was repeated during hypnosis induction and before the exit of the patient from hypnosis.
Category
Treatment - Other

2

Description
Control group: In the usual procedure, lidocaine (1.8 CC Persocaine) with epinephrine 1:100,000) was used for local anesthesia. In this group, no special material or method has been used to increase the rate of wound healing.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Oral and Maxillofacial Medicine Department; Dental Faculty; Mashhad University of Medical Sciences
Full name of responsible person
Rosa Mostafavi Tabatabaee
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Sponsors / Funding sources

1

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Full name of responsible person
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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
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Rosa Mostafavi Tabatabaee
Position
Resident
Latest degree
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Other areas of specialty/work
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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
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
Undecided - It is not yet known if there will be 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
Most data and tables are published when the articles are published
When the data will become available and for how long

After publishing the articles and the satisfaction of other colleagues and professors

To whom data/document is available

After publishing the articles and the satisfaction of other colleagues and professors and also If the person or organization which ask the question is valid and the question remains after the article is published

Under which criteria data/document could be used

After publishing the articles and the satisfaction of all professors and colleagues

From where data/document is obtainable

Rosa Mostafavi Tabatabaee

What processes are involved for a request to access data/document

email or contact after publishing the articles

Comments

This research is a thesis and idea of Dr. Rosa Mostafavi Tabatabai and has been worked on and researched day and night for 4 years. Under the supervision of: First professor: Dr. Majid Sanatkhani (Associate Professor, Department of Oral and Maxillofacial Medicine, Faculty of Dentistry, Mashhad University of Medical Sciences): Chairman of the Khorasan Razavi Association of Oral and Maxillofacial Medicine Second professor: Dr. Mehdi Fathi (Associate Professor, Department of Anesthesiology, Mashhad University of Medical Sciences): Chairman of the Khorasan Razavi and Iran Hypnosis Association Statistical Advisor Professor: Dr. Habibollah Ismaili (Professor, Department of Statistics and Epidemiology, Mashhad University of Medical Sciences)