

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 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

Country

Iran (Islamic Republic of)

Phone

+98 51 3763 8994

Email address

Mostafavitr941@mums.ac.ir

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	
<u>1</u>	
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	
<u>1</u>	
Description of health condition studied	Accelerating of Wound Healing due to Oral Biopsy
ICD-10 code	
ICD-10 code description	
Primary outcomes	
<u>1</u>	
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 questionnaires

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

Street address

Dental Faculty of Mashhad University of Medical Sciences, Vakilabad boulevard

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948959

Phone

+98 51 3882 9501

Fax

Email

mostafavitr941@mums.ac.ir

Web page address

<http://dentistry.mums.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Hossein Bagheri

Street address

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

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948959

Phone

+98 51 3882 9501

Email

pakfetrata@mums.ac.ir

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

Specialist

Other areas of specialty/work

Dentistry

Street address

Dental Faculty; Mashhad University of Medical Sciences; at the beginning of Vakilabad boulevard

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948959

Phone

+98 51 3882 9501

Email

Mostafavitr941@mums.ac.ir

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Rosa Mostafavi Tabatabaee

Position

Oral & Maxillofacial resident in training

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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

Phone

+98 21 2285 3639

Email

Rosamd80@gmail.com

Person responsible for updating data**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Rosa Mostafavi Tabatabaee

Position

Resident of oral and maxillofacial medicine

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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

Phone

8829501 051

Email

Rosamd80@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

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 Sanatkhan (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)