# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

18 Sep 2026

## Anesthetic efficacy of intraoral mucoadhesive Amitriptyline in healthy volunteers

## Protocol summary

**Summary**

This is a randomized, double-blind and placebo-controlled study. Twenty five healthy female volunteers (20 to 40 years old) will be used in this study. Institutional Ethics Committee approval and informed consent from all the volunteers will be obtained. Exclusion criteria include systemic conditions (such as cardiovascular diseases, diabetes, renal insufficiency, hepatic dysfunction .....), allergic reactions to antidepressants, pregnancy, history of nerve injury, receiving drugs, neuropathy. The right or left labial alveolar mucosa of the upper incisor apices will be used for topical anesthesia application. The side will be randomly determined with the table of random numbers. The mucoadhesive amitriptyline and the control patch will be placed on the labial alveolar mucosa and the corresponding contralateral tissue sites. The patches will be kept in for 15 minutes. On removal of mucoadhesive amitriptyline and the control patch, a 27-gauge needle will be inserted into the designated tissue sites. Pain associated with these stimulation testing will be graded by the volunteers on a pain rating score (PRS) as no pain, slight pain, pain, and intolerable pain. In addition, a 10-cm visual analog pain scale (VAS) will be used, with the left end as no pain and the right end as intolerable pain. This protocol will be repeated in 30 and 45 minutes after removal patches.

## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT138706101144N1**
Registration date: **2008-09-29, 1387/07/08**
Registration timing: **prospective**

Last update:
Update count: **0**

**Registration date**

2008-09-29, 1387/07/08

**Registrant information**

**Name**

Mojgan Alaeddini

**Name of organization / entity**

Dental Research Center, Tehran University of Medical Sciences

**Country**

Iran (Islamic Republic of)

**Phone**

+98 88986677

**Email address**

malaeddini@sina.tums.ac.ir

**Recruitment status**

**Recruitment complete**

**Funding source**

Vic-chancellor for research tehran university of medical sciences

**Expected recruitment start date**

2008-10-01, 1387/07/10

**Expected recruitment end date**

2009-10-01, 1388/07/09

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Anesthetic efficacy of intraoral mucoadhesive Amitriptyline in healthy volunteers

**Public title**

Anesthetic efficacy of intraoral mucoadhesive Amitriptyline in healthy volunteers

**Purpose**

Treatment

**Inclusion/Exclusion criteria**
Inclusion Criteria: Women between the ages of 20 and 40 years Exclusion criteria included systemic conditions (such as cardiovascular diseases, diabetes, renal insufficiency, hepatic dysfunction .....), allergic reactions to antidepressants, pregnancy, history of nerve injury, receiving drugs, neuropathy
**Age**
From **20 years** old to **40 years** old
**Gender**
Female

**Phase**
2
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **25**
**Randomization (investigator's opinion)**
N/A
**Randomization description**
**Blinding (investigator's opinion)**
Double blinded
**Blinding description**
**Placebo**
Used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

**1**

**Ethics committee**
**Name of ethics committee**
Ethical and research committee of Tehran university of medical sciences
**Street address**
Tehran university of medical sciences
**City**
Tehran
**Postal code**
**Approval date**
2008-03-15, 1386/12/25
**Ethics committee reference number**
6571-69-64-86

## Health conditions studied

**1**

**Description of health condition studied**
Anesthetic efficacy of intraoral mucoadhesive Amitriptyline in healthy volunteers
**ICD-10 code**
**ICD-10 code description**

## Primary outcomes

**1**

**Description**
Anesthetic
**Timepoint**
15, 30, 45 minutes after removal patches
**Method of measurement**
The pain rating score (PRS) and visual analog scale (VAS) will be measured after insertions of a 27-gauge needle.

## Secondary outcomes

**1**

**Description**
**Timepoint**
At 30 minutes and 24 and 48 hours after the removal of the patch
**Method of measurement**
Local irritation will be rated as follows: 0 = no irritation, 1 = minimal (blood vessels raised above normal levels), 2 = moderate (beet redness of mucosa, individual blood vessels not discernible) and 3 = severe (blister formation and necrosis evident)

## Intervention groups

**1**

**Description**
The right or left labial alveolar mucosa of the upper incisor apices will be used for topical anesthesia application. The side will be randomly determined with the table of random numbers. The mucoadhesive amitriptyline and the control patch will be placed on the labial alveolar mucosa and the corresponding contralateral tissue sites.
**Category**
*empty*

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Dental Reasearch Center of tehran university of medical sciences
**Full name of responsible person**
**Street address**
**City**

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Tehran university of medical sciences

**Full name of responsible person**
Vic-chancellor for research tehran university of medical sciences
**Street address**
keshavars blvd.,Ghods St., Central Office of tehran university of medical sciences, 6th floor
**City**
Tehran
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Tehran university of medical sciences
**Proportion provided by this source**
100
**Public or private sector**
*empty*
**Domestic or foreign origin**
*empty*
**Category of foreign source of funding**
*empty*
**Country of origin**
**Type of organization providing the funding**
*empty*

## Person responsible for general inquiries

**Contact**
**Name of organization / entity**
Dental Reasearch Center
**Full name of responsible person**
Mojgan Alaeddini
**Position**
Asisstant professor
**Other areas of specialty/work**
**Street address**
Ghods St., Enghelab Ave., P.O. Box: 14155-5583, Postal code: 14174
**City**
Tehran
**Postal code**
**Phone**
+98 21 8898 6677
**Fax**
**Email**
malaeddini@sina.tums.ac.ir
**Web page address**

## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
Dental Reasearch Center
**Full name of responsible person**
Mojgan Alaeddini
**Position**
Asisstant professor
**Other areas of specialty/work**
**Street address**
Ghods St., Enghelab Ave., P.O. Box: 14155-5583, Postal code: 14174
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**Web page address**

## Person responsible for updating data

**Contact**

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
*empty*
**Study Protocol**
*empty*
**Statistical Analysis Plan**
*empty*
**Informed Consent Form**
*empty*
**Clinical Study Report**
*empty*
**Analytic Code**
*empty*
**Data Dictionary**
*empty*