Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 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

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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
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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