

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Comparison of the effects of prescription EMLA cream before endoscopy to reduce pain and increase the satisfaction of patients during and after endoscopy, with the effect EMLA gel, Lidocaine gel, Lidocaine spray and placebo gel in endoscopy patients

Protocol summary

Summary

The purpose of this study is determine the level of patient's satisfaction of upper gastrointestinal endoscopy using EMLA cream, EMLA gel, Lidocaine gel, Lidocaine spray and placebo gel and comparison the satisfaction of various groups together. This study design is double-blind clinical trial, considered population includes patients who under upper gastrointestinal endoscopy in Hajar hospital of Shahrekord. The number of patients studied is 150, they are randomly divided into 5 groups of 30 people, including (A, B, C, D and E). The EMLA cream are used five minutes before the endoscopy for Group A, EMLA gel for Group B, Lidocaine gel for group C, Lidocaine spray 1% (3 puffs in posterior part of the tongue) for group D and placebo gel group E that the cream and gel dose is 5 g in posterior part of the tongue for each patient, then patients undergoing upper gastrointestinal endoscopy. Inclusion criteria: upper gastrointestinal endoscopy in these patients should be a non-emergency; no history of upper gastrointestinal endoscopy. Exclusion criteria: age under 12 years; patients with acute gastrointestinal bleeding. Then primary outcome include the satisfaction of patients of endoscopy and secondary outcome include the pain and discomfort in the throat and neck area, the incidence of nausea, vomiting or retching will be examined during and up to half an hour after endoscopy.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201509136480N9**

Registration date: **2015-10-24, 1394/08/02**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-10-24, 1394/08/02

Registrant information

Name

Mohammad Taghi Moradi

Name of organization / entity

Shahrekord University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 38 1334 9509

Email address

mtmoradi@skums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shahrekord University of Medical Sciences

Expected recruitment start date

2006-01-21, 1384/11/01

Expected recruitment end date

2006-06-22, 1385/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of prescription EMLA cream before endoscopy to reduce pain and increase the satisfaction of patients during and after endoscopy, with the effect EMLA gel, Lidocaine gel, Lidocaine spray and

placebo gel in endoscopy patients

Public title

Determine the level of patient's satisfaction of endoscopy using EMLA cream, EMLA gel, Lidocaine gel, Lidocaine spray and placebo gel

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria: upper gastrointestinal endoscopy in these patients should be a non-emergency; the patients have given consent for endoscopy; no history of upper gastrointestinal endoscopy. Exclusion criteria: age under 12 years; lack of consent patient; patients with acute gastrointestinal bleeding; bedridden patients.

Age

From **12 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

In this study sampling method is a table of random numbers.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahrekord University of Medical Sciences

Street address

Shahrekord University of Medical Sciences, Rahmatie, Shahrekord

City

Shahrekord

Postal code

Approval date

2005-11-02, 1384/08/11

Ethics committee reference number

84-8-11

Health conditions studied

1

Description of health condition studied

Pain and dissatisfaction during upper gastrointestinal endoscopy

ICD-10 code

K90, K91,

ICD-10 code description

Other diseases of the digestive system

Primary outcomes

1

Description

The satisfaction of patients of endoscopy

Timepoint

During and after endoscopy

Method of measurement

GHAA-9 questionnaire

Secondary outcomes

1

Description

The pain and discomfort in the throat and neck area

Timepoint

During and after endoscopy

Method of measurement

GHAA-9 questionnaire

2

Description

Vomiting or retching evaluate

Timepoint

During and after endoscopy

Method of measurement

GHAA-9 questionnaire

Intervention groups

1

Description

Intervention group 1: The EMLA cream are used five minutes before the endoscopy for Group A (manufactured by AstraZeneca), the dose is 5 g in posterior part of the tongue.

Category

Treatment - Drugs

2

Description

Intervention group 2: The EMLA gel are used five minutes before the endoscopy for Group B (manufactured by AstraZeneca), the dose is 5 g in posterior part of the tongue.

Category

Treatment - Drugs

3**Description**

Intervention group 3: The Lidocaine gel are used five minutes before the endoscopy for Group C (manufactured by AstraZeneca), the dose is 5 g in posterior part of the tongue.

Category

Treatment - Drugs

4**Description**

Intervention group 4: The Lidocaine spray 1% are used five minutes before the endoscopy for Group D (manufactured by AstraZeneca), the dose is 3 puffs in posterior part of the tongue.

Category

Treatment - Drugs

5**Description**

Intervention group 5: The placebo gel are used five minutes before the endoscopy for Group E (manufactured by AstraZeneca), the dose is 5 g in posterior part of the tongue.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Hajar hospital of Shahrekord

Full name of responsible person

dr Jafar Nasiri

Street address

Hajar hospital, Parastar Street, Shahrekord

City

Shahrekord

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice chancellor for research, Shahrekord University of Medical Sciences

Full name of responsible person

Dr Mahmoud Mobasheri

Street address

Vice Chancellor for research, Shahrekord University of Medical Sciences, Kashani Street, Shahrekord

City

Shahrekord

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice chancellor for research, Shahrekord 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**

Shahrekord University of Medical Sciences

Full name of responsible person

dr Jafar Nasiri

Position

Gastroenterologist

Other areas of specialty/work**Street address**

Shahrekord University of Medical Sciences, Rahmatie, Shahrekord

City

Shahrekord

Postal code**Phone**

+98 38 3333 2907

Fax**Email**

jhnasiri@yahoo.com

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

Shahrekord University of Medical Sciences

Full name of responsible person

dr Jafar Nasiri

Position

Gastroenterologist

Other areas of specialty/work**Street address**

Shahrekord University of Medical Sciences, Rahmatie, Shahrekord

City

shahrekord

Postal code**Phone**

+98 38 3333 2907

Fax
Email
jhnasiri@yahoo.com
Web page address

+98 38 3333 2907
Fax
Email
jhnasiri@yahoo.com
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Shahrekord University of Medical Sciences
Full name of responsible person
dr Jafar Nasiri
Position
Gastroenterologist
Other areas of specialty/work
Street address
Shahrekord University of Medical Sciences, Rahmatie,
Shahrekord
City
Shahrekord
Postal code
Phone

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