

# 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**

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## Person responsible for updating data

### Contact

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**Position**  
Gastroenterologist  
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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*