

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison effect of Morphine and Apotel versus Placebo in relieving pain and final diagnosis and complications from appendicitis in patients with suspected acute appendicitis

#### Protocol summary

##### Summary

Target: The effect of narcotics to patients with suspected acute appendicitis to the final diagnosis and complications from appendicitis. In a clinical trial, a randomized, double-blind (patient and researchers), Non-pregnant patients over 15 years old come to the emergency room of Rasool Akram Hospital with abdominal pain in RLQ that based on history and physical examination are suspicious of acute appendicitis enrolled in the study. Exclude patients who were transferred from another hospital with a diagnosis of appendicitis or patients who received narcotic before hospital and patient with renal failure or Sensitivity to contrast agent of CT scan and patients with the history of trauma. 180 patients enrolled in the study are classified into the three groups (randomly using a table of random numbers) the following will be: 1) Patients on arrival at the emergency receive Placebo (normal saline) 2) Patients on arrival at the emergency receive intravenous Morphine (0.1 mg / kg) 3) Patients at the time of admission receive Apotel (15 mg / kg) At the time of admission to the emergency primary information of patients including demographic and clinical and drug history and current clinical features and symptoms of patients can be collected through interviews and physical examination. In all three group pain intensity is determined with The scoring system Visual Analogue Scale (VAS) Then, the above intervention done by the emergency services. The diagnostic process and tools that used and final diagnosis follow and recorded with executive of plan. Patients who need surgery before entering the operating room again pain intensity is determined based on VAS. Determined and recorded the Complications during and after surgery and diagnosis during surgery. The final diagnosis of appendicitis based on pathology will be after surgery. Patients who do not find the need for surgery in the hospital at least 12 hours and up to 48 hours for

telephone follow-up.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017021531324N2**

Registration date: **2017-05-16, 1396/02/26**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-05-16, 1396/02/26

##### Registrant information

##### Name

Seyed Hamzeh Mousavie

##### Name of organization / entity

Iran University Of Medical Science

##### Country

Iran (Islamic Republic of)

##### Phone

+98 912 296 7445

##### Email address

mousavie.sh@iums.ac.ir

##### Recruitment status

##### Recruitment complete

##### Funding source

Vice Chancellor Of Research, قشدر University of Medical Sciences

##### Expected recruitment start date

2016-04-29, 1395/02/10

##### Expected recruitment end date

2018-03-20, 1396/12/29

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison effect of Morphine and Apotel versus Placebo in relieving pain and final diagnosis and complications from appendicitis in patients with suspected acute appendicitis

**Public title**

The effect of relieving pain in patients with suspected acute appendicitis admission to the final diagnosis and complications from appendicitis in patients of Rasoul Akram Hospital

**Purpose**

Diagnostic

**Inclusion/Exclusion criteria**

Inclusion criteria: Non-pregnant patients; over 15 years old; with abdominal pain in the RLQ and based on the initial history and physical examination are suspicious of acute appendicitis. Exclusion criteria: Patients who were transferred from another hospital with the diagnosis of appendicitis; use relieving pain before they come; patient with renal failure; Sensitivity to contrast agent of CT scans; patients with a history of trauma

**Age**

From **15 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **180**

**Randomization (investigator's opinion)**

Randomized

**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**

Ethics Committee of Iran University Of Medical Science

**Street address**

Near Milad tower, Hemmat highway, Tehran

**City**

Tehran

**Postal code****Approval date**

2016-04-05, 1395/01/17

**Ethics committee reference number**

IR.IUMS.REC 1394.9011216147

**Health conditions studied****1****Description of health condition studied**

acute appendicitis

**ICD-10 code**

K35, K36,

**ICD-10 code description**

Diseases of appendix

**Primary outcomes****1****Description**

abdominal pain

**Timepoint**

when they come to hospital and before they go to OR

**Method of measurement**

VAS analog

**Secondary outcomes****1****Description**

masked symptom with pain relieving

**Timepoint**

during hospitalization

**Method of measurement**

physical exam

**Intervention groups****1****Description**

Intervention group: Amp morphine sulfate 0.1 mg/kg in 10 cc normal saline IV slow injects

**Category**

Diagnosis

**2****Description**

Intervention group: Amp Apotel 15mg/kg in 100 CC normal saline infusion in 20 min

**Category**

Diagnosis

### 3

#### **Description**

control group : vial normal saline 2CC IV stat

#### **Category**

Diagnosis

### **Recruitment centers**

#### 1

#### **Recruitment center**

##### **Name of recruitment center**

Rasool Akram Hospital

##### **Full name of responsible person**

Shabnam Tarahomi

##### **Street address**

Rasool Akram Hospital, Niayesh street, Sattarkhan street

##### **City**

Tehran

### **Sponsors / Funding sources**

#### 1

#### **Sponsor**

##### **Name of organization / entity**

Vice Chancellor Of Research, Iran University of Medical Sciences

##### **Full name of responsible person**

Mrs Irani

##### **Street address**

Near Milad tower, Hemmat highway

##### **City**

Tehran

#### **Grant name**

#### **Grant code / Reference number**

#### **Is the source of funding the same sponsor organization/entity?**

Yes

#### **Title of funding source**

Vice Chancellor Of Research, Iran 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**

Rasool Akram Hospital

##### **Full name of responsible person**

Shabnam Tarahomi

##### **Position**

Intern

##### **Other areas of specialty/work**

##### **Street address**

Plaque 83, Gonabad street, Kokab street, Sattarkhan street

##### **City**

Tehran

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##### **Phone**

+98 21 6643 1917

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### **Person responsible for scientific inquiries**

#### **Contact**

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### **Person responsible for updating data**

#### **Contact**

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##### **Full name of responsible person**

Shabnam Tarahomi

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## **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*