

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)

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+98 912 296 7445

Email address

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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

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Position

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Fax

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Web page address

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