

Randomized trial of Alvarado score and antibiotics therapy as a corporate protocol versus conventional clinical management for acute appendicitis

Submission date 23/02/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 02/04/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 30/10/2008	Condition category Digestive System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Mohammadreza Farahnak

Contact details

Department of Surgery, 22 Bahman Hospital
Imam street
Masjedsaleiman
Iran
19674

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Study objectives

This study aims to compare incorporating the Alvarado score and outpatient antibiotics with conventional clinical management in the treatment of acute appendicitis.

Ethics approval required

Old ethics approval format

Ethics approval(s)

22 Bahman Hospital ethics committee, approved on 16 May 2006. Ref: 1014/19

Study design

Randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Diagnostic

Participant information sheet

Health condition(s) or problem(s) studied

Acute appendicitis

Interventions

The patients will be randomized according to a computer-generated randomization list into case and control group. The Alvarado score is calculated for both groups by a general practitioner not involved in other stages of the study. The Alvarado scores of the patients in the control group will not be known to the admitting service and surgical team. They will continue with conventional clinical assessment and management. The admitting service and the surgical team are informed of the Alvarado scores of patients in the case group. Afterward, patients of the case group will be divided into 3 management subgroups according to their own Alvarado scores: Subgroup 1 - Alvarado score 4 or less. Discharge, no follow up. Subgroup 2 - Alvarado score 5 to 7. Outpatient antibiotics and observation if practicable. They will be prescribed one dose of intravenous gentamicin, 6 mg/kg, and metronidazole, 500 mg for adults or 15 mg/kg as a loading dose for children. Afterward, patients will be discharged on a 10-day course of co-amoxiclav 625 tablets 3 times daily for adults and oral suspension of co-amoxiclav 312.5, 25 mg /kg per day in divided doses every 8 hours for children (Farabi Pharmaceutical Co, Iran). They will be asked to attend 1 day in the clinic. Subgroup 3 - Alvarado score 8 to 10. Immediate operation.

They will be immediately arranged to undergo emergency surgery after intravenous injection of antibiotics loading dose as mentioned above.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

1. Time to surgery, from randomization to skin preparation in hours
2. Duration of hospitalization, from randomization to discharge from hospital or emergency service (for out-patients) in hours

Secondary outcome measures

1. Admission rate
2. Operation rate
3. Nontherapeutic surgeries rate (surgery is called therapeutic when it finds the cause of patient's pain and it is pertinent to cure the problem)
4. Perforation with late treatment (PLT) rate (treatment that begins at least 10 hours after randomization is considered late)

Overall study start date

10/07/2006

Completion date

01/04/2007

Eligibility**Key inclusion criteria**

1. Older than 6 years
2. Admitted initially for the current abdominal pain

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

188

Key exclusion criteria

1. Generalized peritonitis
2. Suspected of having any abdominal mass or any abdominal involvement of degenerative or systemic diseases

3. Evidence of any mental disturbances, acute confusional state, or dementia
4. Already have any imaging document including plain radiography, ultrasonography, or computed tomographic scan
5. Patients, childrens parent(s), or admitting surgeon repudiate entry into the study

Date of first enrolment

10/07/2006

Date of final enrolment

01/04/2007

Locations

Countries of recruitment

Iran

Study participating centre

Department of Surgery, 22 Bahman Hospital

Masjedsoleiman

Iran

19674

Sponsor information

Organisation

Bahman Hospital (Iran)

Sponsor details

Department of Surgery

22 Bahman Hospital

Imam street

Masjedsoleiman

Iran

1967

Sponsor type

Hospital/treatment centre

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Department of Surgery, 22 Bahman Hospital (Iran)

Funder Name

Department of Surgery, Iran University of Medical Sciences (Iran)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications	publication	01/09/2007		Yes	No