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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

Registration date
02/04/2007

Overall study status
Completed

Last Edited
30/10/2008

Condition category
Digestive System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

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

Primary study design
Interventional

Study design
Randomized controlled trial

Study type(s)
Diagnostic

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(s)
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

Key secondary outcome(s)
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)

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

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

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)

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

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