

Comparison of clinical judgement and Alvarado score in the diagnosis of acute appendicitis

Submission date 13/07/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 19/09/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 05/09/2014	Condition category Digestive System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Appendicitis is a painful swelling of the appendix, a finger-like pouch connected to the large intestine. The Alvarado score is a clinical scoring system used in the diagnosis of appendicitis. In our study we want to compare the sensitivity and specificity of the Alvarado score and the clinical judgement made by our doctors.

Who can participate?

Patients aged over 18 presenting at the outpatient ward of the Surgical Department of the University of Szeged with suspected acute appendicitis.

What does the study involve?

Participants undergo an ultrasound examination in our Radiology Department. They are then divided into two groups. The groups alternate between weeks A and B. In week A the decision for treatment is based on the Alvarado score: the patient is either sent home, stays in hospital for observation, or is operated on. In week B the decision for treatment is based on the clinical judgement of the chief surgeon.

What are the possible risks and benefits of participating?

There are no risks to the participants, as the chief surgeon has the right to overrule the treatment based on the Alvarado score in week A, if the surgeon thinks that it isn't reliable. These patients are excluded from the trial.

When is the study starting and how long is it expected to run for?

The study started in August 2011 and is expected to run for a year and a half, or until 250 patients have been recruited.

Who is funding the study?

Department of Surgery, University of Szeged, Hungary.

Who is the main contact?

Professor György Lázár
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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

SZ001

Study information

Scientific Title

Alvarado score versus clinical judgement in the diagnosis of acute appendicitis: a prospective, randomized controlled trial

Study objectives

Our aim is to investigate the value of Alvarado score system in comparison with conventional clinical judgement

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee of University of Szeged, ref: 49/B-180/2010 KK

Study design

Prospective randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Diagnostic

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Acute appendicitis

Interventions

We are planning to recruit 125 patients into each group, until we recruit approximately 250 participants. In each group we take the patient's history, physical examination, body temperature (rectal-axillar), white blood cell level, US examination. We calculate the Alvarado point of recovery patient.

In group A the further therapy depends on this point (1-4 emission, 5-6 observation, 7-10 laparoscopic or open appendectomy).

In group B the leading surgeon decides the therapy of the patient without reference of the Alvarado point. After appendectomy we check the pathological finding, call back the patient one week after the operation, and one year after it to a control examination.

In case of emission without operation, we make a control one year after the appearance in our emergency room, to find out if the symptoms or complaints are still occurring.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Specificity, sensitivity and positive predictive value of Alvarado score vs clinical judgement.

Secondary outcome measures

Measure the specificity and sensitivity of US examination practice in our department

Overall study start date

01/09/2011

Completion date

01/09/2012

Eligibility

Key inclusion criteria

1. Patients aged 18 or older, who present in our Surgical Department with right quadrant abdominal pain are included in our study
2. Every participant should be able to read through an information sheet and sign a consent form

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

250

Key exclusion criteria

1. Does not meet inclusion criteria
2. Those who refuse the participation in our study

Date of first enrolment

01/09/2011

Date of final enrolment

01/09/2012

Locations**Countries of recruitment**

Hungary

Study participating centre

Pécsi u. 6.

Szeged

Hungary

6720

Sponsor information**Organisation**

University of Szeged (Hungary)

Sponsor details

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Sponsor type

University/education

Website

<http://www.u-szeged.hu/english/>

ROR

<https://ror.org/01pnej532>

Funder(s)**Funder type**

University/education

Funder Name

Research Foundation of the University of Szeged (Hungary) - Department of Surgery

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