

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

<b>Submission date</b> 13/07/2011	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 19/09/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 05/09/2014	<b>Condition category</b> 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

Prof Lázár György

## Contact details

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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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+36 (0)62 545 462

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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