Participant Information

Ultrasound in patients with acute abdominal pain in the emergency department

Principal investigator	**Ronja Leth Larsen** Physician, PhD student Research Center for Emergency Medicine, Aarhus University Emergency Department, Regional Hospital Horsens
Trial sites	Emergency departments in Horsens, Aarhus, Gødstrup, Viborg, Esbjerg and Holbæk

PURPOSE

The purpose of the trial is to investigate whether an ultrasound examination of the abdomen, as part of the doctor's initial examination, helps the doctor make a more accurate diagnosis in patients with acute abdominal pain.

TREATMENT

Half of the included patients receive the standard examination. The other half receive the standard examination plus an ultrasound examination of the abdomen.

Allocation to the two groups is random.

PARTICIPATION

Consent to take part in the trial means that we collect information about you during this admission. This has no effect on your treatment.

Your participation lasts only while you are admitted to the emergency department. After the trial has ended, a group of specialist physicians will read your medical record to assess your diagnosis.

ORIGINAL TITLE

Effect of point-of-care ultrasound on correct preliminary diagnosis in adult emergency department patients with acute abdominal pain: A multicenter, controlled, randomized trial

We would like to ask whether you would like to take part in a scientific trial. Before you decide whether to take part, you should fully understand what the trial involves and why we are conducting it. We therefore ask you to read this participant information carefully.

You will have a conversation with the doctor, in which this participant information will be explained in more detail and where you can ask any questions you have about the trial. The conversation about the trial takes place in a quiet place in the emergency department, and you have the right to bring a companion or to ask for an independent assessment. If you decide to take part in the trial, we will ask you to sign a consent form. Before you decide whether to sign the consent form, you have the right to time for reflection. Because the trial takes place in an acute situation, the time for reflection will be shorter than in planned trials. You will be given as much time as possible without it affecting your treatment. You can always decline to take part, and you can withdraw your consent at any time without giving a reason and without consequences for your treatment.

Purpose of the trial

The project will investigate whether an ultrasound examination of the abdomen in patients with acute abdominal pain, as part of the doctor's initial examination, enables the doctor to diagnose patients more accurately. We do this by comparing the doctor's initial diagnosis with the final diagnosis determined by an expert panel.

Methods and practical organization of the trial

Patients with abdominal pain can take part in the trial, which is a randomized trial in which chance decides whether you receive the standard examination of the abdomen performed by the doctor, or whether an ultrasound examination is added to the standard examination. When you are admitted to the emergency department, you will be examined by a doctor shortly after arrival. If you are in the group that receives an ultrasound examination, it will be performed by a doctor in the emergency department who has been trained in the examination.

The ultrasound examination takes 5-10 minutes and takes place right after the examination of your abdomen. The result of the ultrasound examination forms part of the doctor's assessment and may influence further investigations and treatment. After your examination, your doctor will complete an online questionnaire. Based on his or her assessment and examinations with or without ultrasound, the doctor will write down what he or she thinks is wrong with you.

Your active participation in the trial lasts only while you are admitted to the emergency department, and your investigations and treatment are at all times the responsibility of the treating physician. A group of specialists in emergency medicine, surgery or radiology will review your medical record for up to 30 days after your discharge to determine the final diagnosis, which the trial uses for comparison.

You can take part if you are 18 years or older, present to the emergency department with acute abdominal pain, can communicate in Danish or English, and are able to give informed consent.
You cannot take part if you have previously taken part in the trial, if the cause of your abdominal pain is already known (e.g., known gallstones or known abdominal cancer that explains the pain), if you have already been examined by a doctor for the current abdominal pain during the same visit, if you have had your abdomen examined for the same symptoms within the past 7 days, if you have had abdominal pain for more than 3 months and the current visit is a worsening of this long-standing condition, or if you need immediate intensive care.

A total of 508 patients will take part in the trial, from emergency departments in Horsens, Aarhus, Gødstrup, Viborg, Esbjerg and Holbæk.

Risks of the trial

There are no known side effects associated with the ultrasound examination itself. However, the examination may cause brief discomfort, as the doctor presses the ultrasound probe against your abdomen, which may be tender if you have abdominal pain. If you are in the group that receives an ultrasound examination, you may receive either fewer or more examinations than you otherwise would have. Some of these follow-up examinations, e.g., CT scans, involve exposure to X-ray radiation. Previous studies have shown that ultrasound makes doctors either equally good or better at diagnosing patients with abdominal pain. We therefore do not expect participation in the trial to increase the risk of misdiagnosis.

There may be risks associated with the research project that we do not yet know about. If we discover side effects that we have not already informed you about, you will of course be informed. You will then have the opportunity to decide whether you still wish to take part in the study.

Other treatment options

Depending entirely on your condition and what the doctor thinks may be wrong with you, there are many examinations that can be used to investigate acute abdominal pain. Regardless of which group you are in, the doctor can order the examinations that are clinically necessary. The ultrasound examination in the trial does not replace these examinations, but may supplement the doctor's initial assessment.

Information from your medical record

If you consent to take part, researchers affiliated with the project will obtain the necessary information from your medical record, including the electronic health record.

- Background information: Age, sex, smoking habits and alcohol consumption
- Health status: Any chronic diseases and height/weight
- The current visit: Blood pressure, pulse and temperature, where the pain is located, and the time of the examination
- The doctor's assessment before the examination: The doctor's expectation of whether an ultrasound examination will contribute to the diagnosis
- The doctor's assessment after the examination: The preliminary diagnosis, possible alternative diagnoses, the doctor's certainty about the diagnosis, any findings on the ultrasound examination, and which group you have been randomized to
- Examinations: Results of any imaging (e.g., ultrasound, CT), blood tests, microbiological samples and tissue samples, as well as any unexpected findings
- Treatment: The treatment you receive during your course of care
- The final diagnosis: After at least 30 days, a group of independent specialists will review your medical record to determine the final diagnosis and assess whether the treatment was appropriate. The final diagnosis is the one the trial uses for comparison.

The information is used to:

- Describe the patients taking part in the trial
- Compare how accurately doctors make the correct diagnosis with and without ultrasound
- Investigate whether ultrasound is most useful in the patients in whom the doctor expects in advance that it will help
- Determine the final diagnosis and assess the overall course of treatment
- Ensure the quality of the trial by checking the collected data

The information is used solely for research purposes within this project.

By giving your consent, you give the principal investigator, the sponsor and the sponsor's representatives, as well as any regulatory authorities, direct access to information in your medical record, including the electronic health record. This access is used to view the information about your health that is necessary to conduct, monitor and audit the trial. Everyone with access to the medical record is bound by a duty of confidentiality, and the information is processed in accordance with applicable legislation.

Processing of your personal data

Central Denmark Region and Aarhus University are the data controllers for the processing of your personal data in the trial. The data are processed in accordance with the General Data Protection Regulation and the Danish Data Protection Act and are stored in a secure research database, where you are identified by a unique trial number instead of your name and CPR number (Danish personal identification number). Only researchers affiliated with the project have access to the data. As a general rule, data are stored for at least 5 years after publication of the trial results, in accordance with good scientific practice. Your data will not be transferred to countries outside the EU/EEA.

Benefits of the trial

When patients come to the emergency department with abdominal pain, it is important that they receive the correct diagnosis, preferably at the doctor's first examination. This is so that they can receive the right treatment as quickly as possible, and so that they can go home if they do not have a condition that requires treatment. If it turns out that doctors become better at diagnosing patients correctly when they use ultrasound, this should become part of the standard examination.

There is no certain, direct benefit to you as a participant in the trial. If you are in the group that receives an ultrasound scan, the doctor's assessment may become more accurate sooner, which could potentially mean fewer additional examinations and faster treatment. However, this is exactly the question the trial is designed to answer, and there is currently no scientific evidence that the ultrasound group receives better treatment than the control group.

Regardless of which group you are in, you will receive the standard treatment you would normally receive in the emergency department. Your participation will contribute to the future treatment of patients with acute abdominal pain.

Exclusion from and termination of the trial

If you no longer meet the criteria for taking part, or if the treating physician considers that it is no longer safe for you to continue, you will be withdrawn from the trial. No monitoring or other measures will be established that could lead to the project as a whole being stopped before the planned number of patients has been included.

Information about financial matters

The trial is an investigator-initiated academic study. Principal investigator Ronja Leth Larsen, physician and PhD student, and sponsor Jesper Weile, physician, PhD and associate professor, have jointly initiated the trial together with a group of collaborating Danish emergency physicians. The study has no commercial sponsor. The principal investigator receives a salary during the project period, but otherwise the investigators have no financial interests in the study.

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Participants receive no payment. You are covered by the Danish Patient Compensation Association (Patienterstatningen) in the same way as during ordinary treatment at the hospital.

Time for reflection

As the trial takes place in an acute situation, the time to consider whether you wish to take part may be limited. How much time you have depends on how quickly your treatment needs to start.

You will be given as much time as possible without it affecting your treatment. At a minimum, you will always have the time it takes the doctor to fetch the ultrasound machine, which corresponds to at least 5 minutes. If your condition is not time-critical, you may have up to several hours while the doctor sees other patients.

The time for reflection is an offer. If you are ready to take part straight away, you do not need extra time. The doctor will make sure that you do not feel pressured to give consent. You can always decline to take part and can withdraw your consent at any time without consequences for your treatment.

More information about the study

If you would like to know more about the trial, you can visit the trial website at akutmave.dk. Here you can read more about the background and purpose of the trial, and about the results when they become available. You are also always welcome to contact the principal investigator (see contact details below).

We hope that this information has given you sufficient insight into what it means to take part in the trial, and that you feel prepared to make a decision about your possible participation. We also ask you to read the enclosed material "The rights of a trial participant in a health science research project".

Kind regards

Ronja Leth Larsen
Physician, PhD student, principal investigator

Jesper Weile, PhD, clinical associate professor, specialist physician, Emergency Department, Regional Hospital Horsens
Physician, PhD, associate professor, sponsor

Contact

Ronja Leth Larsen · Physician, PhD student
Emergency Department, Regional Hospital Horsens, Sundvej 30, 8700 Horsens
Phone: +45 53 60 91 04 Email: ronlar@rm.dk