

# Can magnetic resonance imaging give more information than computed tomography in the assessment of acute pancreatitis?

<b>Submission date</b> 21/09/2021	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 25/11/2021	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 25/11/2021	<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

Acute pancreatitis (AP) is inflammation of the pancreas. In this condition, the digestive juices produced by the pancreas are inappropriately activated, which leads to (partial) destruction of the tissues of the pancreas. AP is diagnosed when two of the following criteria are present: (a) sudden onset of abdominal pain radiating to the back, (b) elevated pancreatic blood marker, i.e. three times beyond the upper limit of normal values, or (c) characteristic findings of AP on imaging. The latter is mostly performed with computed tomography (CT) or, rarely, with magnetic resonance imaging (MRI). The aim of this study is to find out whether MRI is a valid alternative to CT and offers more detailed information than CT in the initial assessment of AP thanks to a recently developed MR sequence called T2 mapping.

### Who can participate?

Patients aged over 18 years diagnosed with AP in the visceral surgery department at the Lausanne University Hospital (CHUV), Switzerland, during the period between December 2020 and November 2021

### What does the study involve?

Participants undergo a CT scan within 48-72 hours of admission to assess the severity of AP and an additional MRI scan. The MRI findings will be compared with the CT scan results.

### What are the possible benefits and risks of participating?

The benefits of the study are based on the inherent higher contrast resolution of MRI images compared to CT images. MRI can sometimes define the cause of AP such as gallstones or pancreatic duct abnormalities that are usually not seen on CT. In addition, MRI offers a better characterization of abdominal collections caused by the AP which can potentially change treatment if they need to be drained. Patients will contribute to advancing research on the diagnosis of AP that may lead to an improvement of the treatment of future patients. Acute pancreatic oedema could be exactly quantified using T2 mapping, providing a clue for the patients' prognosis.

According to current knowledge, MRI does not involve any health risks. The only risk factors are

related to certain metals that are incompatible with MRI, to body implants and to the contrast medium. Therefore, patients with certain metallic implants, a known allergy to contrast medium or kidney failure will not be able to participate in this study. Very rarely, brief side effects such as minor allergic reactions may be observed, or claustrophobia (anxiety when in a confined space), dizziness and phosphenes (sensation of light flashes) may occur. However, the rate of severe allergic reactions related to gadolinium (Dotarem), the contrast agent used in this study, is estimated to be between 0.06% and 0.2% only, which is much rarer than those observed with CT contrast media. The additional MRI sequence (T2 mapping) does not present any additional danger for patients.

Where is the study run from?

University Hospital of Vaud (CHUV) (Switzerland)

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

May 2020 to November 2021

Who is funding the study?

University Hospital of Vaud (CHUV) (Switzerland)

Who is the main contact?

Prof. Sabine Schmidt Kobbe

Sabine.Schmidt@chuv.ch

## Contact information

**Type(s)**

Scientific

**Contact name**

Prof Sabine Schmidt Kobbe

**ORCID ID**

<https://orcid.org/0000-0003-2631-3032>

**Contact details**

Service de radiodiagnostic et radiologie interventionnelle

Centre hospitalier universitaire Vaudois – CHUV

Rue du Bugnon 46

Lausanne

Switzerland

1011

+41 (0)79 556 06 44

Sabine.Schmidt@chuv.ch

## Additional identifiers

**Clinical Trials Information System (CTIS)**

Nil known

**Protocol serial number**

## Study information

### Scientific Title

Computed tomography and magnetic resonance imaging in the assessment of acute pancreatitis, a comparative study

### Acronym

CTMRIAP

### Study objectives

The hypothesis is that magnetic resonance imaging (MRI) is a valid alternative to computed tomography (CT) and even offers more detailed information than CT in the initial assessment of acute pancreatitis (AP) thanks to the recently developed MR sequence T2 mapping:

1. MRI is at least as effective as CT in assessing AP.
2. MR findings (i.e. quantitative values obtained by T2-mapping) correlate with the length of the patients' hospital stay.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Approved 02/12/2020, Vaud Ethics Committee (CER-VD commission cantonale d'éthique de la recherche sur l'être humain, Avenue de Chailly 23, 1012 Lausanne, Switzerland; +41 (0)21 316 18 30; secretariat.CER@vd.ch), ref: 2020-02153

### Study design

Interventional prospective non-randomized single-arm monocentric study

### Primary study design

Interventional

### Study type(s)

Diagnostic

### Health condition(s) or problem(s) studied

Acute pancreatitis

### Interventions

Each patient will undergo a CT examination with intravenously injected contrast medium administration within 48-72 hours of admission to assess the severity of AP.

Patients who signed our consent form will undergo an additional MR examination with the intravenous injection of the contrast agent Dotarem. All patients will be scanned in a supine position using an 18-channel body array coil and a 32-channel spine coil. MR parameters include axial (3 mm) and coronal (3 mm) Half-Fourier Acquisition Single-shot Turbo Spin Echo (HASTE) MR sequences, an axial (6 mm) diffusion-weighted MR sequence (DWI), axial T1-weighted MR sequences VIBE) (3 mm) before and after the intravenous injection of 0.2 cc/kg of gadoteric acid, Dotarem and a heavily T2-weighted sequence in the coronal oblique plane centered on the main

pancreatic duct (MR-Wirsungography) with Relaxation Enhancement (RARE) centered on the head and tail of the pancreas).

Finally, a recently developed, T2 mapping prototype sequence will be acquired in the axial plane as follows: a multi-echo spin-echo (MESE) prototype sequence will be used to acquire a 10-fold undersampled k-space using prospective acquisition correction (PACE) with external triggering (15 slices,  $0.8 \times 0.8 \times 5$  mm resolution,  $\Delta TE/TR/TA$  10.6 msec/2.2 sec/2:39 min). According to the individual trigger efficiency of a patient, the MR technician will choose either a phase scout or a 1D navigator at the liver dome to trigger the acquisition on end-expiration, thus allowing free breathing for the patients. For the reconstruction of T2 maps, a combination of generalized auto-calibrating partially parallel acquisition (GRAPPA) and model-based accelerated relaxometry by iterative nonlinear inversion (MARTINI), termed GRAPPATINI, will be employed. Furthermore, synthetic T2-weighted images with different simulated echo times ( $TE = 40/100/150$  msec) will be generated by applying the forward signal model onto the quantitative maps.

Two radiologists with 5 and 15 years of experience in abdominal MRIs, respectively, will analyse the MR images blinded to the CT examination. AP severity assessment will be graded according to the severity index. Furthermore, in order to quantify acute edema of the pancreatic gland (reflecting the degree of pancreatitis) the two radiologists will determine the T2 values (median and SD) of the pancreatic parenchyma by manually drawing one region of interest (ROI) in each head, body, and tail. They will draw the largest possible ROI in each area, while avoiding the pancreatic duct, vessels, focal lesions, and zones showing clear partial volume effects.

After the MR image analysis, the MR findings will be compared with the CT results.

### **Intervention Type**

Procedure/Surgery

### **Primary outcome(s)**

AP severity graded according to the severity index on CT and MRI within 48-72 hours of admission

### **Key secondary outcome(s)**

AP severity assessed clinically using the Ranson score, laboratory values and the further clinical evolution of pancreatitis during hospitalisation

### **Completion date**

30/11/2021

## **Eligibility**

### **Key inclusion criteria**

1. Patients diagnosed with AP in the visceral surgery department at the Lausanne University Hospital (CHUV), Switzerland, during the period between December 2020 and November 2021. According to the guidelines, AP is defined as two or more of the following characteristics: abdominal pain, and serum amylase or lipase levels three or more times the upper limit of normal ( $>210$  U/L and  $>180$  U/L, respectively).
2. Patients undergoing a contrast-enhanced CT during their hospital stay about 48-72 hours after admission

### **Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

1. Intubation and/or ventilation
2. Renal failure with estimated glomerular filtration rate (GFR) less than 30 ml/min/1.73 m<sup>2</sup>)
3. History of allergic reactions to any contrast media
4. Proven or suspected pregnancy
5. Age under 18 years
6. General exclusion criteria for MRI:
  - 6.1. Patients with non-MRI compatible metallic or electronic implants, devices or metallic foreign bodies (shrapnel, cochlea implants, neurostimulator, or other non-MRI compatible implants)
  - 6.2. Non-MRI compatible cardiac pacemaker
7. Previous diagnosis of chronic pancreatitis
8. Inability to cooperate because of claustrophobia
9. Inability to cognitively and/or linguistically understand the patient consent sheet
10. Patients with missing clinical or radiological data

**Date of first enrolment**

02/12/2020

**Date of final enrolment**

30/11/2021

**Locations**

**Countries of recruitment**

Switzerland

**Study participating centre**

**Lausanne University Hospital (CHUV)**

Rue du Bugnon 46

Lausanne

Switzerland

1011

# Sponsor information

## Organisation

University Hospital of Lausanne

## ROR

<https://ror.org/05a353079>

# Funder(s)

## Funder type

Other

## Funder Name

Investigator initiated and funded

# Results and Publications

## Individual participant data (IPD) sharing plan

Trial and participant data is handled with uttermost discretion and is only accessible to authorised personnel who require the data to fulfil their duties within the scope of the study. The MRI and CT images will be stored on the server of the CHUV. Each examination will be scored on the case report form (CRF). The CRF will be completed by handwriting to ensure traceability. The CRF will be kept in a locked safe to which only authorized persons will have access.

## IPD sharing plan summary

Not expected to be made available

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol file</a>	version 4	03/10/2021	11/10/2021	No	No