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

Submission date	**Recruitment status**	[_] Prospectively registered
21/09/2021	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
25/11/2021	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
25/11/2021	Digestive System	[_] 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?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
2020-02153

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

Primary study design
Interventional

Study design
Interventional prospective non-randomized single-arm monocentric study

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 × 0.8 × 5 mm resolution, ΔTE/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 m²)
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)
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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?
Protocol file	version 4	03/10/2021	11/10/2021	No	No