The detrimental course of acute intestinal ischemia: improvement of the diagnosis

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Gastrointestinal vascular conditions
Study type	Observational invasive

Summary

ID

NL-OMON52596

Source
ToetsingOnline

Brief title
TACTIC trial

Condition

- Gastrointestinal vascular conditions
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
Bowel ischemia, Mesenteric Ischemia

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Maag Lever Darm Stichting (MLDS)

Intervention

Keyword: Biomarker panel, Diagnosis, Intestinal ischemia, Volatile organic compound (VOC)

Outcome measures

Primary outcome

The primary endpoint of the study is the early and accurate identification of presence and severity of acute intestinal ischemia in patients. The main study parameters are plasma biomarkers indicative for intestinal damage of patients suspected of acute intestinal ischemia.

Secondary outcome

The secundary study paramater is the identfication of volatile organic compounds (VOC) in exhaled air of patients suspected of acute intestinal ischemia.

Study description

Background summary

Acute intestinal ischemia is a life-threatening condition with a short-term mortality that can range up to 80%. Medical diagnosis and treatment have remained troublesome, due to the clinical presentation which is mostly characterized by non-specific signs and symptoms. Early unambiguous diagnosis of acute intestinal ischemia is critical to prevent progression from reversible to irreversible intestinal injury, and henceforth decrease morbidity and improve survival.

Study objective

We aim to validate a panel of plasma biomarkers and investigate volatile biomarkers that potentially allow early and accurate identification of acute intestinal ischemia in patients. Second, we aim to identify a volatile organic compound (VOC) profile specific for acute intestinal ischemia in exhaled breath.

Study design

Prospective observational study

Study burden and risks

There is a minimal amount of risks involved in participating in this study. Blood samples will be obtained with the use of an arterial line, intravenous line (IV), central venous catheter (CVC), peripheral venous catheter (PVC) or a venepuncture. The risk of venepuncture is a small local hematoma. In addition to blood sampling, we will also obtain exhaled air. This non-invasive procedure takes approximately 5 minutes in which patients breath in a 3L Tedlar bag at a normal frequency and volume. This procedure will not cause any physical strain. Collection of samples and data will take place during the hospital stay of the included patients. For this reason, no additional hospital visits are required for this study. Participating patients in this study will have no direct benefits, but in the future the results of our study will likely be useful in the early diagnosis of patients suspected of acute intestinal ischemia.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

The following inclusion criteria will be used:

Age >= 18 years

All consecutive patients admitted to one of the participating medical centers emergency departments (ED) or at the intensive care unit (ICU) (see 4.1 Population Base) with clinical suspicion of acute intestinal ischemia, which is based on;
o clinical manifestation;
o physical examination by the physician;
o laboratory measurements;
o physician*s consideration to perform computed tomography (CT)-scan

Exclusion criteria

Younger than 18 years of age

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	18-09-2020
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	04-09-2019
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	20-03-2020
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL68026.068.19