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How well certain signs in the body (biomarkers) can help doctors figure out if someone has a condition where blood flow to their abdomen is not working properly (abdominal ischemia).

Submission date
04/04/2023

Recruitment status
No longer recruiting

Registration date
23/06/2023

Overall study status
Completed

Last Edited
23/06/2023

Condition category
Digestive System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Acute mesenteric ischemia (AMISH) is an urgent medical condition resulting from the blockage of the superior mesenteric artery at its beginning or in the proximal part at the junction or in its peripheral branches. Some triggers and disease states in which obstruction is more common are known. Currently there aren`t well-defined clinical and laboratory prognostic factors that could be used to predict the course of the disease. The use of serum markers in the diagnosis of AMISH is quite limited. Given the high heterogeneity between studies, it is difficult to suggest a single marker for AMISH diagnosis.
Treatment of AMI in the early stages of the disease may be endovascular, with no known prognostic factors to predict the course of the disease, the extent of ischemia, and possible subsequent complications due to re-supply of blood in the same nourishing area. There are no clear recommendations in the literature for appropriate therapeutic action.

The purpose of the research is to analyze clinical, biochemical and radiological factors that could be used to predict the course of the disease, the occurrence of complications and the short-term and long-term consequences of superior mesenteric artery occlusion (AMISH).

Who can participate?
Adult (person over the age of 18) with acute mesenteric ischemia who are willing to participate, without any hematological, oncological or immunological disorder.

What does the study involve?
The study will involve patients who have acute mesenteric ischemia, which will be diagnosed using clinical presentation, radiological methods, and blood analysis. The patients will be divided into three groups, including two investigative groups and a control group. The investigative groups will receive either non-surgical or surgical treatment, while the control group will not have acute mesenteric ischemia. Blood samples will be taken at admission, diagnosis, and at various points during treatment to analyze factors like time since onset, medical history,

medications, and specific blood markers. Patients in the surgical treatment group will also undergo a histopathological analysis of the resected bowel, and the results will be compared to blood samples from the other groups.

What are the possible benefits and risks of participating?
With the help of participating patients, we will be able to have a more precise insight and better understanding the importance of markers in the diagnosis of acute mesenteric ischemia. By comparing different diagnostic tools and analysis, we hope to indicate the course of the disease and may change the course of diagnostic and therapeutic algorithms in the occurrence of acute mesenteric ischemia (AMISH). There isn`t a health hazard for participation.

Where is the study run from?
This study is ongoing at the Abdominal Surgery Department and Clinical Institute of Radiology at the University Medical Center of Ljubljana (Slovenia)

When is the study starting and how long it is expected to run for?
November 2020 to December 2023

Who is funding the study?
University Medical Center Ljubljana (Slovenia)

Who is the main contact?
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Study information

Scientific Title

Predictive value of biomarkers for the assessment of intestinal ischemia

Acronym
AMISH

Study objectives
H1. The concentration of observed markers is related to the degree and duration of ischemia.
H2. The concentration of the observed markers is related to the radiological criteria that determine the degree of ischemia.
H3. The release of the observed biomarkers in the superior mesenteric artery is due to ischemia, due to obstruction of the lumen; the concentration of markers in mixed peripheral venous blood and in the area of narrowing (intraarterial) is different due to the different mechanism of ischemia.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 03/11/2020, Komisija Republike Slovenije za medicinsko etiko (Commission of the Republic of Slovenia for Medical Ethics, Štefanova ulica 5, 1000 Ljubljana; +386 1 478 69 06; kme.mz@gov.si), ref: 0120-379 / 2020-5

Primary study design
Observational

Study design
Single center observational cohort study

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Early prediction and diagnosis of acute mesenteric ischemia

Interventions
The prospectively planned study will include patients in whom acute mesenteric ischemia will be demonstrated by clinical presentation, radiological methods (ultrasound, CT - computed tomography, CTA - CT angiography), analysis of blood factors. Depending on the course of the disease, patients will be divided into two investigative groups and a control group:
1. Investigative group: non-surgically treated patients with interventional radiology techniques.
2. Investigative group: surgically treated patients who will be operated on with known and established surgical techniques (exploratory laparotomy, segmental resection of the ischemic bowel with anastomosis / terminal stoma, re-delayed laparotomy).
3. Control group: patients who do not have acute mesenteric ischemia and in whom we will determine the level of observed chemical factors in the peripheral blood.

A blood sample will be taken at admission and diagnosis of AMISH, 24 hours after.
The level of observed markers will be removed in the observed groups 24 hours after diagnosis of AMISH regardless of the type of therapeutic response and in patients with delayed re-exploratory laparotomy before reoperation and 48 hours after exploratory laparotomy when bowel resection is not required.

Among the observed factors we will analyze:
*Time since the onset of clinical signs of the disease (ischemic pain);
*Anthropometric factors,
*Associated diseases,
*Drug treatment,
*Bioimpedance measurements,
*Differential blood status, LDH, AST, ALT, Fibrinogen, activated partial thromboplastin time, INR, CRP, PCT, D-dimer, I-FABP, D-Lactate, IL-6, Citrulline, DAO, GLP-1, VEGF, HIF1A.

Histopathological analysis of the resected bowel will be performed in patients in study group 2; we will determine specific histopathological indicators and the level of Il-6 in the tissue sample. The results will be compared with the level of observed factors in the peripheral venous blood and in patients from the first study group from a blood sample from the superior mesenteric artery, which will be taken during the intervention.

Statistical data analysis will be performed: multivariate model of logistic regression, Mann - Whitney test for nonparametric variables and analysis of variables, t-test for parametric variables, Cox regression, model for survival analysis and identification of predictive factors. If the sample is large enough, we will additionally use data mining.

Intervention Type
Not Specified

Primary outcome(s)
Measured by blood sample at baseline and 24 hours:
Differential blood status, LDH, AST, ALT, Fibrinogen, activated partial thromboplastin time, INR, CRP, PCT, D-dimer, I-FABP, D-Lactate, IL-6, Citrulline, DAO, GLP-1, VEGF, HIF1A

Key secondary outcome(s)
Measured using patient records at single time point:
1. Body weight (kg), Height (cm), BMI (kg/m²)
2. Symptom and medication history
3. Pain intensity (VAS 0 - 10) and duration
4. Findings from CT angiography of abdomen and pelvis
5. Surgical treatment, complications, follow up surgery
6. Lenght of stay (days)

Completion date
31/12/2023

Eligibility

Key inclusion criteria
1. Age: Over 18 years
2. Consent to take part

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Oncological disorders
2. Immunological disorders
3. Hematological disorders

Date of first enrolment
20/12/2022

Date of final enrolment
31/12/2023

Locations

Countries of recruitment
Slovenia

Study participating centre
University Medical Center Ljubljana
Zaloska cesta 2
Ljubljana
Slovenia
1000

Sponsor information

Organisation
Ljubljana University Medical Centre

ROR
https://ror.org/01nr6fy72

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Ljubljana University Medical Centre

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from:
Assistant Dr. Aleksandar Zafirovski
aleksandarzafirovski5@gmail.com

IPD sharing plan summary
Available on request