Potency of Antiplatelet Drugs in MAFLD

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON21913

Source
NTR

Brief title
PAD-MAFLD

Health condition

Metabolic dysfunction Associated Fatty Liver Disease

Sponsors and support

Primary sponsor: UMCG
Source(s) of monetary or material Support: 1st flow of funds (UMCG/RUG)

Intervention

Outcome measures

Primary outcome

Change in platelet function after in vitro administration of active metabolites of antiplatelet drugs (aspirin, clopidogrel, ticagrelor) to the blood of patients with various stages of fibrosis due to MAFLD, compared to healthy controls. To estimate platelet function, we will assess platelet adhesion by Flow Based Adhesion, platelet activation by Flow Cytometry, and platelet aggregation by Whole Blood Aggregation.

Secondary outcome

Baseline values, such as body weight, height, medical history, use of medications, use of alcohol, smoking status will be assessed. Parameters to define stage of steatosis and fibrosis due to MAFLD will be assessed with the use of a FibroScan (Controlled Attenuation Parameter Scores (dB/m) and FibroScan Fibrosis Score (kPa)). Other parameters involved in assessing the hemostatic status consist of markers for activation of platelets and coagulation (platelet factor 4, prothrombin fragment 1+2, thrombin-antithrombin complex), routine blood tests (platelet count, hemoglobin, von Willebrand factor, fibrinogen, prothrombin time, international normalized ratio, activated partial thromboplastin time).

Study description

Background summary

Rationale: The aetiology of approximately 40% of all patients with cirrhosis is metabolic dysfunction associated fatty liver disease (MAFLD) – a percentage that is expected to only increase in the next decades. In addition to liver-related morbidity and mortality, there is a close relationship between MAFLD and risk of cardiovascular disease. Primary or secondary prevention of cardiovascular events generally consist of lifestyle advice, optimisation of blood glucose levels and blood pressure, use of statins and use of antiplatelet drugs. However, both platelet levels and platelet function appear to be altered in patients with chronic liver disease, which raises the question whether current strategies as used in the general population might be sufficient for this specific patient group.
Objective: To investigate the in vitro effect of clinically used antiplatelet drugs on platelet adhesion, activation and aggregation in patients with MAFLD.
Study design: A prospective cross-sectional, mono-center study.
Study population: One hundred and twenty patients with various stages of MAFLD, who have given informed consent will be included in this study. In addition, forty healthy controls will be recruited to establish reference values for the various tests employed.
Intervention (if applicable): The grade of liver steatosis and fibrosis will be determined by transient elastography (FibroScan). Blood samples (27 mL) will be drawn by venepuncture at the same time of routine blood tests.
Main study parameters/endpoints: The extent by which platelet reactivity decreases after in vitro addition of various active metabolites of antiplatelet drugs. Platelet reactivity will be assessed prior to and after addition of antiplatelet drugs by flow-based platelet adhesion assays, whole blood platelet aggregation tests, and flow cytometry-based approaches.

Study objective

Platelet activity of patients with MAFLD after addition of antiplatelet drugs in vitro is similar to that of patients without MAFLD.

Study design

After verbal consent, the participant will be approached during their regular outpatient clinic

appointment where the Informed Consent form can be signed and the participant can be included. Each participant will undergo an interview, blood sampling and FibroScan once, either right before or after their regular outpatient clinic appointment. For the participant, the study ends after these procedures have been completed.

Intervention

The grade of liver steatosis and fibrosis will be determined by transient elastography (FibroScan). Blood samples (27 mL) will be drawn by venepuncture at the same time of routine blood tests.

Contacts

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Eligibility criteria

Inclusion criteria

Inclusion criteria study groups:
• ≥ 18 years of age
• Signed informed consent
• Some degree of liver steatosis and fibrosis (F1-F4) with or without diagnosis of diabetes mellitus type 2

Inclusion criteria control group:
• ≥ 18 years of age
• Signed informed consent

Exclusion criteria

• Underlying liver disease with other aetiology than MAFLD
• Use of anti-platelet (salicylates, P2Y12 inhibitors, dipyridamole) or anti-hemostatic (heparins, vitamin K antagonists, direct oral anticoagulants) drugs
• Use of Non-Steroid Anti-Inflammatory Drugs 4 days prior to inclusion
• Documented history of hereditary thrombophilia or haemophilia
• Current malignancy
• Pregnancy
• Pre-existing immunosuppressive status (HIV positivity, previous solid organ transplant)
• Transfusion of blood products 7 days prior to inclusion
• Not willing to be notified of FibroScan results

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	22-10-2021
Enrollment:	160
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL9826
Other	METc UMCG : 2021/411

Study results