Potency of Antiplatelet Drugs in MAFLD

Gepubliceerd: 22-10-2021 Laatst bijgewerkt: 13-12-2022

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

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON21913

Bron
NTR

Verkorte titel
PAD-MAFLD

Aandoening

Metabolic dysfunction Associated Fatty Liver Disease

Ondersteuning

Primaire sponsor: UMCG
Overige ondersteuning: 1st flow of funds (UMCG/RUG)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• 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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	22-10-2021
Aantal proefpersonen:	160
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9826
Ander register	METc UMCG : 2021/411

Resultaten