Neutrophil migration in gluten-related diseases

Gepubliceerd: 14-07-2020 Laatst bijgewerkt: 19-03-2025

In gluten-related diseases, neutrophil function in response to gluten challenge is different. These differences may allow to develop a novel less invasive assay to diagnose gluten-related disease.

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

Samenvatting

ID

NL-OMON29405

Bron
Nationaal Trial Register

Verkorte titel
Granrose

Aandoening

Celiac disease; Non-celiac gluten sensitivity

Ondersteuning

Primaire sponsor: Maastricht University
Overige ondersteuning: Maastricht University, EU

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Our primary goal is to confirm the differences in neutrophil migration behaviour between control and CD patients as observed in the American study, for the Dutch situation, and to

add to the study a third group, NCGS patients, in order to get insight in both gluten-related diseases allowing us to develop a diagnostic kit based on the obtained results.

For this purpose, part of the blood that will be collected once by venepuncture (using EDTA tubes) during the single visit will be used to set up the 2D-underagarose migration assay to investigate neutrophils migration to gluten in these three study groups.

Toelichting onderzoek

Achtergrond van het onderzoek

The main objective of this study is to investigate the migratory behaviour of neutrophils isolated from healthy individuals and gluten-related disease patients' blood to develop a diagnostic tool for gluten-related diseases that can replace biopsy and detect a gluten-associated disease even if the patient is on a gluten-free diet.
Our secondary objective is to find biomarkers associated with neutrophil immune function by the determination of expression levels of cell-specific immune mediators.

This is a cross-sectional pilot/proof-of-concept study. Participants visit the MUMC+ once for a blood draw (32 mL – 3x 8mL EDTA-tubes and 1x 8mL serum collection-tube) by venepuncture and completion of a questionnaire. The blood sample will be used for a 2D-underagarose migration assay, RNA sequencing, determination of haplotype HLA-DQ2/DH8 and serological tests on celiac markers at the time of blood collection.

Doel van het onderzoek

In gluten-related diseases, neutrophil function in response to gluten challenge is different. These differences may allow to develop a novel less invasive assay to diagnose gluten-related disease.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

N/A

Contactpersonen

Publiek

Maastricht University
Marlijne de Graaf

+31 6 55 74 10 96

Wetenschappelijk

Maastricht University
Marlijne de Graaf

+31 6 55 74 10 96

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Adult volunteers, aged 20-60 years old, who belong to one of the following groups:
1. Healthy volunteers without celiac disease (CD) or non-celiac gluten sensitivity (NCGS), who do not state any symptoms after ingesting gluten (n = 20);
2. Biopsy-proven CD patients in remission, on a strict gluten-free diet since at least three months (n = 10);
3. NCGS patients reporting gastrointestinal or extra-intestinal symptoms within 8 hours after gluten consumption, in whom celiac disease has been ruled out by means of serology and/or biopsy and who are on a gluten-free diet since at least three months (n = 10).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Gastrointestinal, genitourinary or immune diseases that can affect interpretation of the results;
- Use of antibiotics or immunosuppressive drugs within 90 days prior to the study;
- Excessive use of drugs or alcohol;
- Participation in any other scientific study that may interfere with the present study.

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:	01-01-2021
Aantal proefpersonen:	40
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 54481
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9183
CCMO	NL74741.068.20
OMON	NL-OMON54481

Resultaten