Neutrophil migration in gluten-related diseases

No registrations found.

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

Summary

ID

NL-OMON29405

Source
Nationaal Trial Register

Brief title
Granrose

Health condition

Celiac disease; Non-celiac gluten sensitivity

Sponsors and support

Primary sponsor: Maastricht University
Source(s) of monetary or material Support: Maastricht University, EU

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

We intend to find a panel of biomarkers associated with the migration capacity by performing RNA sequencing in all three study groups, using part of the blood sample that will be collected by venepuncture (using EDTA tubes) during the single visit. This approach largely increases the possibility to find shared values and differences between the groups and allows us to get better understanding of the underlying mechanisms that are at the basis of the observed neutrophil migration behavior.

Since virtually all CD patients carry HLA-DQ2/DQ8 haplotypes (>97%) we will determine these haplotypes in our participants in order to properly define the study groups. We will also measure celiac markers in serum at time (using the blood collected in the 8mL serum collection-tube) of assay as an essential check for the in-remission state of the disease in CD patients and to exclude CD in our healthy control group.

Study description

Background summary

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.

Study objective

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.

Study design

N/A

Intervention

N/A

Contacts

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Eligibility criteria

Inclusion criteria

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).

Exclusion criteria

- 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.

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):	01-01-2021
Enrollment:	40
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 54481
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

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

Study results