Better control and treatment of Ulcerative Colitis (UC) by exploring the universe of microenvironment imposed tissue signatures and their correlates in liquid biopsies

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The main aim of this project is to obtain a better control and treatment of immune-mediated diseases by exploring the universe of microenvironment imposed tissue signatures and their correlates in liquid biopsies.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Gastrointestinal inflammatory conditions
Study type	Observational invasive

Summary

ID

NL-OMON54471

Source
ToetsingOnline

Brief title
Immuniverse WP5-UC

Condition

- Gastrointestinal inflammatory conditions

Synonym
Inflammatory bowel disease, Ulcerative Colitis

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Horizon 2020;IMI Innovative Medicine Initiative

Intervention

Keyword: biomarker profile, immune mediated disease, therapy, ulcerative colitis

Outcome measures

Primary outcome

The main aim of this project is to obtain a better control and treatment of

immune-mediated diseases by exploring the universe of microenvironment imposed

tissue signatures and their correlates in liquid biopsies

Secondary outcome

not applicable

Study description

Background summary

Immune-mediated diseases are extremely diverse - patients with the same diagnosis may see the disease progress in very different ways, and respond differently to treatments. This is because the course of the disease is influenced by multiple factors, including the patient's genes, immune system, environment, and the microbes living in !heir gut. Furthermore, all of these factors interact with and impact on one another. As a result, it is very hard to predict how the disease will develop in a specific patient, and which treatments will be effective.
Hence, mechanistic understanding of this heterogeneity and biomarkers predictive for disease control and therapy response over time are important prerequisites of a future precision medicine in IMIDs. ImmUniverse has been formed as a European transdisciplinary consortium to tackle these unmet needs and to understand the role of the crosstalk between tissue microenvironment and immune cells in disease progression and response to therapy of ulcerative colitis (UC) and atopie dermatitis (AD).
The consortium will combine analysis of tissue-derived signatures with

"circulating signatures" detectable in liquid biopsies, employing state-of-the-art profiling technologies
to provide new validated diagnostics in IMID that are expected to improve patient management, lead to increased patient well-being and will significantly reduce the socioeconomic burden of these diseases.
Immuniverse Work Package 5 (WP5) will validate the disease pathway -and mechanism signatures identified in the multi omic discovery WP2 in immune cells in affected tissue and peripheral blood. WP5 aims to further substantiate our understanding of the immunemediated gut disease ulcerative colitis (UC). WP5 will use liquid biopsies (peripheral blood), affected and non-affected gut biopsies to generate transcriptome, proteome, DNA-methylome and mi RNA signatures of immune cell subsets and analyse the association between immune cells circulating in peripheral blood and the microenvironment of gut tissue
Also this WP aims to develop a protocol to analyse and sort living immune cells from cryopreserved tissue. Ultimately, the project's findings should contribute to a better, more precise diagnosis for patients; and better information on how severe the disease is likely to be for each individual patient and how it will progress over time. The project overall aim is to improve disease stratification, successful treatment selection and therapy follow-up (early detection of side effects or non-responsiveness).

Study objective

The main aim of this project is to obtain a better control and treatment of immune-mediated diseases by exploring the universe of microenvironment imposed tissue signatures and their correlates in liquid biopsies.

Study design

This is a study in which patients donate extra blood and gut biopsies once during a regular outpatient clinic visit.

Study burden and risks

The patients are seen during their regular outpatient visits.
- Sampling (once) of additional biopsies (4x inflamed tissue, 4x non inflamed tissue) during a regular colonoscopy will take approximately 10 minutes
- Drawing of 4 additonal blood tubes (once) during a regular blood test will take approximately 10 minutes.
- We do not expect any complications of these procedures.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Diagnosis of Ulcerative Colitis
- Age >= 18 years
- Willing and able to comply with the study related procedures
- Present in the hospital for an already scheduled colonoscopy visit
- Provide signed informed consent

Exclusion criteria

- Age <= 18 years
- Unable to give informed consent
- Unable or unwilling to comply with study-related procedures
- Patients without uninflamed tissue during a sigmoidoscopy or colonoscopy (we would like to replace these excluded patients with a maximum of 10 patients)

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	10-05-2022
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO Date:	10-11-2021
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	16-02-2022
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	23-03-2022
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	08-11-2022
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	

Date:	08-05-2023
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
CCMO	NL78552.091.21