Healthy control nose blood

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to compare data from nose brush cells and blood cells from CF patients, obtained in the TERRIFIC studie, to the data in healthy controls.

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON51830

Source
ToetsingOnline

Brief title
HCNB

Condition

- Other condition

Synonym
-

Health condition

alle deelnemers zijn gezond

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W,TAAI

Intervention

Keyword: Healthy control, scientific research, volunteers

Outcome measures

Primary outcome

Expression levels of inflammatory markers expressed on epithelial and immune cells, abundance of a particular pathogenic cell type in peripheral blood or plasma levels of inflammatory proteins like cytokines. The inflammatory response of epithelial cells in vitro to pathogens and the interplay between the epithelial cells and immune cells obtained from blood in in vitro co-cultures. Outcomes of these parameters will be a direct comparison to the outcomes of the TERRIFIC study.

Secondary outcome

not applicable

Study description

Background summary

Scientific research conducted at the laboratory of Pulmonary Medicine of the Erasmus Medical Center includes translational research on immunology, oncology and vascular diseases. To interpret new findings in patients diseased patients, comparison with age matched healthy controls in necessary.

Epithelial cells respond to pathogens in our direct environment by secreting inflammatory mediators that activate the underlying immune cells to exert an inflammatory response that ultimately leads to pathogen clearance. In respiratory diseased, including Cystic Fibrosis (CF) and asthma, the epithelial - immune cell interplay in these diseases, the use of primary healthy material as a comparison is pivotal. We will use nose brushes for epithelial cell isolation and blood for the isolation of immune cells. We will measure expression levels of markers expressed on epithelial and immune cells, abundance of pathogenic cell types in nasal brushes and blood, the presence of

inflammatory proteins and we will exploit organoid cultures to investigate the epithelial-immune cell interactions in healthy individuals as a direct comparison to the TERRIFIC study investigating CF patients. The research protocol to obtain nose brushes and blood from CF individuals (TERRIFIC protocol) was already approved in May 2022. The approval of the current HCNB protocol would allow us to directly compare data obtained from CF individuals to healthy controls and would aid in identifying possible therapeutic intervention strategies.

Study objective

to compare data from nose brush cells and blood cells from CF patients, obtained in the TERRIFIC studie, to the data in healthy controls.

Study design

Single Centre Cohort study.

Study burden and risks

Participants will be asked for one blood sample of 60mL, drawn by peripheral venous puncture at the Pulmonary Medicine laboratory or outpatient clinic. Also, patients are asked to undergo a nasal brush. Furthermore, data on sex, age, smoking- and relevant medical history are recorded. Risks of participation are negligible, as these procedures are minimally invasive and safe. Healthy volunteers will not have any personal benefit from participating but help increase scientific knowledge on respiratory diseases in general. Participating is completely voluntary, not participating in research will not influence the way employees or patients and their accompanying partners are treated in any way.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
- Age >= 18 years old
- not included in ongoing clinical studies
- Signed informed-consent

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
- refusal of participation
- known respiratory or autoimmune disease
- treatment with immune suppression

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Other

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-10-2022
Enrollment:	100
Type:	Anticipated

Ethics review

Approved WMO

Date:	25-10-2022
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL80535.078.22