T cells in Nose of Older adults (TINO)

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24946

Source NTR

Brief title TINO

Health condition

Respiratory infections, Aging

Sponsors and support

Primary sponsor: LUMC **Source(s) of monetary or material Support:** NWO-ENW (KLEIN)

Intervention

Outcome measures

Primary outcome

To compare nasal CD8+ T cell frequency between young adults and frail older adults.

Secondary outcome

1. In depth profiling of T cells in nose and blood of young adults and older adults with and without frailty.

2. Assess the stability of T cell populations and other immune populations over time.

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3. Compare blood and nasal T cells between older adults with and without recurrent respiratory tract infections.

4. Compare other nasal and systemic immune populations and parameters between young adults, vital older adults and frail older adults (with or without recurrent infections).5. Associate nasal and systemic factors (e.g. cytokines and metabolites) and with T cells.

6. Associate respiratory tract microbiota with T cells and other immune parameters.

7. Associate covariates, such as biological age, HLA type and sex with T cells and other immune parameters.

8. Assess the impact of acute respiratory tract infection on (antigen-specific) T cell populations and other immune parameters in nose and blood.

Study description

Background summary

Rationale: Individuals with advanced age are at a progressively increasing risk of acquiring lower respiratory tract infections. Besides calendar age, the degree of frailty also associates with increased susceptibility to pneumonia requiring hospitalization. How alterations in the mucosal immune system with advanced age predispose to infections remains unclear as access to relevant tissue samples is limited. With minimally-invasive nasal sampling methods, we recently observed that in vital older adults, both CD4+ T cells and CD8+ T cells are selectively lost from the nasal mucosa. However, the exact phenotype, underlying mechanisms, key molecules and consequences of this have not yet been investigated. Objective: Here, we aim to elucidate the mechanisms underlying the loss of nasal T cells and characterize in depth the differences of T cells in young and older adults and associate this loss with susceptibility to infections

Study objective

Reduced numbers of specific CD8+ T cell subsets in frailty elderly correlate with a limited ability to mount robust mucosal T cell responses to control and clear respiratory infections

Study design

*day of recruitment

*2-4 months after recruitment

(when respiratory infection occurs within study time-frame, than we will sample at: moment of infection, 1, 3 and 5 months after infection)

Intervention

N/A

Contacts

Public Leiden University Medical Center Wesley Huisman

31 71 526 1455 **Scientific** Leiden University Medical Center Wesley Huisman

31 71 526 1455

Eligibility criteria

Inclusion criteria

• Healthy elderly (>65yrs) that are not frail (frailty score 1-3)

• Frailty (frailty score \geq 4) elderly (>65yrs) These will be consist of individuals without a history of recurrent respiratory infections or with >2 self-reported episodes of respiratory infection in the past year.

• Healthy young (18-35yrs) adults

Exclusion criteria

- Incompetence to provide informed consent prior or during study
- Current smoker or >40 pack year history
- · History of severe nose bleedings
- Diagnosed with asthma, COPD or chronic rhinosinusitis
- Use of inhalation corticosteroids or antibiotics in the past 6 weeks
- Current use of anti-coagulants (to prevent nosebleeds)
- Respiratory tract infection or common cold in the past 2 weeks
- Immunocompromised individuals (with primary immune deficiency or secondary immune deficiency)
- Life expectancy <28 days in the opinion of study physician
- Vaccination in the 2 months prior to study start

A potential subject that is only excluded from participation based on a recent vaccination will be asked to re-participate 2 months post vaccination.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Factorial
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-11-2021
Enrollment:	170
Туре:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Ethics review

Positive opinion	
Date:	
Application type:	

18-10-2021 First submission

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
NTR-new	NL9796
Other	METC LDD : METC NL77841.058.21

Study results