Immune responses in a rural to urban gradient: identifying geographical footprints of the immune system to improve vaccine development

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Primary Objective: * To compare the expression of Th1 and Th2 from Europeans with those of Africans living in urban, semi urban and rural areas.Secondary Objective: * To explore the functional phenotypes of Th1 and Th2 using mass cytometry cells as...

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

Summary

ID

NL-OMON48968

Source
ToetsingOnline

Brief title
Geographical differences in immune responses

Condition

- Other condition

Synonym
Enivronmental factors, exposure

Health condition

Immunological profile; enviromental exposure

Research involving

Human

Sponsors and support

Primary sponsor: Cheikh Anta Diop University of Dakar
Source(s) of monetary or material Support: EUROPEAN & DEVELOPING COUNTRIES CLINICAL TRIALS PARTNERSHIP

Intervention

Keyword: Geographical differences, Immune system, Urban rural, Vaccine

Outcome measures

Primary outcome

Primary endpoint

* The percentages of interleukin (IL-) 4, IL-5, IL13 cytokine producing CD4+ T cells as indicator of Th2 response and interferon gamma (IFNg) producing CD4+ T cells as Th1 cells, in PBMC from Europeans with those of Africans living in urban, semi urban and rural areas

Secondary outcome

Secondary endpoint

* Characterization of PBMCs in terms of lineages of T cells, B cells, monocytes and dendritic cells as well as innate lymphocytes and their subsets and clusters in Europeans in addition to Africans living in urban, semi urban and rural areas.

Exploratory endpoints

* Data set on transcriptome of cells identified to pay a determining role in European, African rural, semi urban and rural profiles.

* Combined analysis of the high dimensional data obtained by mass cytometry and

RNA sequencing

* Establishment of SOPs to be used at the Cheikh Anta Diop University in

Senegal for further investigation of vaccine responses

Study description

Background summary

As the immune system is central to the success of vaccines and because of the recent indications that strong geographical differences may define immunological footprints, assessment of the environmental impact on the immune system need to form an integral part of any serious attempt for vaccine development. Indeed, in studies comparing immune responses of rural and urban Africans as well as matched Europeans, we have shown that there are major differences that cannot be accounted for by genetic variation only .

Study objective

Primary Objective:
* To compare the expression of Th1 and Th2 from Europeans with those of Africans living in urban, semi urban and rural areas.

Secondary Objective:
* To explore the functional phenotypes of Th1 and Th2 using mass cytometry cells as well as their transcriptional signature following environmental settings
* To analyse the high dimensional data obtained by mass cytometry and RNA sequencing
* Training in complex immunological analysis of samples

Exploratory Objective:
* To explore the transcriptional signature of cells following environmental settings
* To analyse the high dimensional data obtained by mass cytometry and RNA sequencing
* Training in complex immunological analysis of samples

Study design

This is a prospective cohort study involving rural, semi-urban, and urban populations with long term differential environmental exposures that are suspected to impact the development of the immune system. We will gather data on the exposure period to each environmental setting from individual questionnaires at time of inclusion. Sampling will only be performed at baseline through a single venipuncture procedure.

Study burden and risks

For the whole study, participants will only need the clinic once for venipuncture and filling out the questionnaires. The only physical interventions in this study involves collection of venous blood that may be associated with a slight pain and discomfort due to the middle penetration but those regress within minutes. There are no direct benefits for the volunteers

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:
- Living in the urban, semi-urban or rural setting preferably lifelong (not less than 10 years)
- Be 18-40 years of age

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:;- Any history of diabetes, arterial hypertension, chronic renal failure
- Signs or history of infection at the time of inclusion
- Any history or clinical signs of inflammatory diseases

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-07-2019
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	28-06-2019

Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL66287.058.18