A pilot study to characterize the effects of ageing on the innate immune response against influenza

Published: 24-06-2008
Last updated: 08-05-2024

Characterization of the effects of ageing on the innate immune response against influenza.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Viral infectious disorders
Study type	Observational invasive

Summary

ID

NL-OMON31944

Source
ToetsingOnline

Brief title
Ageing and the innate immune response against influenza

Condition

- Viral infectious disorders

Synonym
flu, Influenza

Research involving
Human

Sponsors and support

Primary sponsor: Nederlands Vaccin Instituut
Source(s) of monetary or material Support: min. VWS

Intervention

Keyword: ageing, dendritic cell, influenza, innate immunity

Outcome measures

Primary outcome

To determine functional immune responses, after in vitro influenza infection of dendritic cells isolated from young adults and elderly people. The responses will be characterized based on; influenza-specific mRNA expressiom, maturation molecule expression, inhibitory molecule expression, cytokine production and T cell stimulating capacity.

Secondary outcome

To determine the variation of the assays for qualifying the innate immune response of DC isolated from young adults or elderly individuals.

Study description

Background summary

Influenza cause high morbifdity and mortality rates in the elderly population (> 65 years). There are indications that the function of the immune system decreases with increasing age, and that this results in a decreased protection against influenza infections in the elderly. For the induction of protective immune responses after vaccination against influenza, the innate immune response as provided by dendritic cells (DC) is of great importance. The DC steer the influenza specific T cells by presenting the viral antigens. It is therefore necessary to gain more insight into the effect of ageing on DC function. The gained knowledge of this study will support the development of new and/or improved vaccines against influenza for specifically the elderly population.

Study objective

Characterization of the effects of ageing on the innate immune response against

influenza.

Study design

This study has been designed as an observational study. Subjects from two groups, i.e. healthy young adults and healthy elderly, will be recruited by the Julius Center at the UMC Utrecht or RIVM/NVI. Each subject will be screened for the in- and exclusion criteria. From each participant, 60 ml of blood will be drawn once for isolation of peripheral blood mononuclear cells (PBMC), which will be used for the culturing of monocyte-derived DC. The DC will be infected in vitro with influenza and subsequently tested for phenotypic and functional immune response. Responses from young and elderly will be compared.

Study burden and risks

Possibly hematoma, pain from blood drawing. Participation in this study will support the development of improved vaccines against influenza for the elderly.

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

Subjects have to fulfil all the following criteria:
- 20-40 years or >= 65 years old
- vaccinated with most recent seasonal influenza vaccine
- having a signed informed consent form

Exclusion criteria

The exclusion criteria are:
- immune deficiencies
- haematological disorders
- bleeding disorders
- usage of anticoagulants, corticosteroids, NSAIDs and/or statins
- diabetes mellitus

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	30-09-2008

Enrollment:	94
Type:	Actual

Ethics review

Approved WMO Date:	24-06-2008
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	10-03-2009
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL22965.041.08