The effect of cold exposure on influenza induced immune responses

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determine the effect of cold exposure on influenza induced immune responses

Ethical review	Approved WMO
Status	Pending
Health condition type	Viral infectious disorders
Study type	Interventional

Summary

ID

NL-OMON44547

Source
ToetsingOnline

Brief title
Influence cold

Condition

- Viral infectious disorders

Synonym
common cold, flu, Influenza viral infection

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cold, Immune response, Influenza

Outcome measures

Primary outcome

comparison of cytokine responses after ex-vivo whole blood stimulations before

and after cold exposure.

Secondary outcome

Compare complete blood counts before and after cold exposure

Study description

Background summary

The amount of people infected with the influenza virus varies throughout the year, with most infections occurring during wintertime. From a large cohort study we have learned that immune responses of isolated immune cells of healthy volunteers during wintertime are less responsive to influenza stimulation compared to those isolated during summertime. This seasonal effect was specific to influenza and a handful of other pathogens, whereas most pathogens showed no seasonal effect. The decreased responsiveness to influenza in winter indicates that increased host susceptibility could be one of the reasons for the seasonality of influenza infections. This susceptibility could be influenced by various environmental factors. Two of the most significant environmental differences between summer and winter are temperature and precipitation. Cold in particular has been shown to be a modulator of the immune system. However, the direct effect of cold on ex vivo influenza induced immune responses has never been studied before. This study will investigate the effect of cold exposure on immune responses induced by influenza. As a reference we will also include a pathogen that does not show seasonal infection rates. We speculate that cold exposure decreases the immune responses induced by influenza, and that this effect is less pronounced in the non-seasonal reference pathogen.

Study objective

determine the effect of cold exposure on influenza induced immune responses

Study design

single arm interventional study

Intervention

all participants exposed to a cold water bath. Before and after cold exposure blood will be drawn to analyze changes in immune responses.

Study burden and risks

Burden of the study will include venapuncture before and after cold exposition to a 16 degrees water bath of a duration of 4 minutes. Both are considered to have minimum risk. There will be no benefit for participants.

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

Healthy
Older than 18 years of age
Written Informed consent

Exclusion criteria

Medical history associated with immunodeficicency, cardiovascular events or cardiac rhythm disorders or chronic diseases. Chronic use of immunosuppressives or NSAID's, acute illness within 2 weeks prior to start of the study. Substance abuse defined as drug use within the last 12 hours or blood alcohol percentage above 0.05

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	18-08-2017
Enrollment:	175
Type:	Anticipated

Ethics review

Approved WMO

Date:	03-08-2017
Application type:	First submission
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	NL62160.091.17