The seroepidemiology of mumps in a highly vaccinated population of university students in the Netherlands

Published: 17-01-2011
Last updated: 10-08-2024

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

Summary

ID

NL-OMON34179

Source
ToetsingOnline

Brief title
Mumps seroepidemiology among students

Condition

- Viral infectious disorders

Synonym
mumps

Research involving
Human

Sponsors and support

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

Intervention

Keyword: mumps, serology, students

Outcome measures

Primary outcome

In the first analysis, the primary study parameter will be the measured mumps titers in the paired serumsamples in the group that has claimed to have had a clinical mumps infection. As a controle on the natural behaviour of MMR antibody titers after several years, also measles and rubella titers will be measured in the same multiplex ELISA at the RIVM.

In a second analysis, the occurence of clinical mumps (based on the questionnaire) and subclinical mumps (based on a similar titerrise as in the group with clinical mumps) is the primary study parameter. In this case, the effect of the mumpstiters on the occurence of mumps will be investigated.

Secondary outcome

As secondary parameters the relation between the number of MMR vaccines (0, 1 of 2) will be related to the mumpstiters in the first serum sample.

Study description

Background summary

Since December 2009, the incidence of mumps has increased in the Netherlands. The majority of cases are among students who have been vaccinated with at least one dose of MMR vaccine.

Mumps vaccination is included in the Dutch National Immunisation Programme (Rijksvaccinatieprogramma (RVP)). The outbreak among Dutch students might be

caused by waning immunity, in combination with specific social factors that are characteristic for this group.

Study objective

The objective of this study is to gain insight into the occurence of mumps in a, presumed, highly immune student population, both clinical and subclinical mumps. Furthermore, there shall be an attempt to calculate the 'correlate for protection' (the immunity level (antibodies or cellular immunity) of an individual above which he/she is protected against infection).

Research questions:
1. What are the mumps antibody titers in a large group of 2e, 3e en 4e yr medical students?
2. Is there a realtionship between mumps antibody titers and given vaccinations?
3. Is there a realtionship between mumps antibody titerknetics and the occurence of clinical mumps?
4. What percentage of students has had a subclinical mumpsinfection (based on mumpstiter kinetics)?
5. Which antibodytiter against mumps in the first bloodsample gives protection against (clinical) mumps?

Study design

The study is a retrospective follow-up study conducted among medical students, in which a questionnaire and paired serumsamples for mumps antibody testing are obtained from participants.

The study populationd exists of medical students in Leiden, who are in their second, third or fouth year of college. Besides a questionnaire and serumsampling, these students are asked for their permission to analyse a pre-exposure blood sample which is systematically stored as part of the HBV vaccination programme at the start of their medicine study.
The questionnaire contains question regarding vaccination-status, some riskfactors for mumps and questions on clinical signs of mumps.

Study burden and risks

The individual participant does not benefit from participating in this study. He/she does benefit indirectly since the study aims to improve the National Immunisation Programme, and it is only a small effort which is needed from the participants.

There is negligible risk associated with the venapuncture for blood collection.

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

Medical students (2nd, 3rd, 4th year) from the LUMC.

Exclusion criteria

No exclusion.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-01-2011
Enrollment:	250
Type:	Actual

Ethics review

Approved WMO

Date:	17-01-2011
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	NL33696.058.10