A study of humoral and cellular-mediated immune response in Monoclonal gammopathy of Undetermined Significance after vaccination with trivalent inactivated influenza vaccine (influvac)

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The questions to be answered are:1. Is vaccination with trivalent inactivated influenza vaccine in MGUS patients useful? ; Do these patients elicit adequate humoral and cellular T-cell responses after influenza vaccination?2. What is the B cell...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Plasma cell neoplasms
Study type	Interventional

Summary

ID

NL-OMON34204

Source
ToetsingOnline

Brief title
mgus-vacc respons

Condition

- Plasma cell neoplasms

Synonym
MGUS, Monoclonal gammopathy of undetermined significance

Research involving

Human

Sponsors and support

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

Intervention

Keyword: humoral, immunity, MGUS, vaccination

Outcome measures

Primary outcome

Humoral immune response will be determined by the Haemagluttination inhibition test and respose is defined by the achievement of titres >40, which are considered protective.

Enzyme linked ImmunoSPOT (ELIspot) will also quantify influenza specific B cell response.

the cellular immune response will be measured by Intracellular Cytokine (i.e. IFN*, IL-2 and TNFα) detection by Flow Cytometry and assessment of proliferation of CD4 and CD8 T cells by Flow Cytometry.

these parameters in patients will be compared to healthy controls

Secondary outcome

not applicable

Study description

Background summary

Monoclonal Gammopathy of Undetermined Significance (MGUS) is a pre-malignant condition characterised by the limited clonal expansion of transformed bone marrow plasma cells with no clinical manifestations. MGUS is present in 3% of people over 50 and has a lifelong risk of progression to Multiple Myeloma or related plasma cell disorders.
Vaccination against influenza is recommended for the elderly and is not contraindicated in MGUS. However, there is little information concerning the efficacy of vaccination in MGUS. The humoral response to infection in MGUS patients is also unclear. They have normal levels of polyclonal immunoglobulins in the serum but the degree of immunosuppression if at all is unknown and therefore it is unclear whether they have compromised humoral response. To our knowledge, no studies have been published on the efficacy of vaccination against influenza virus with he currently used subunit vaccines in MGUS patients.
In this context, we designed a study protocol to determine the humoral and cell-mediated immune responses following influenza vaccination.

Study objective

The questions to be answered are:
1. Is vaccination with trivalent inactivated influenza vaccine in MGUS patients useful? ; Do these patients elicit adequate humoral and cellular T-cell responses after influenza vaccination?
2. What is the B cell proliferation relation to clonal growth? ; What happens to the plasma cell clones after vaccination?

Study design

This is an observational study whereby the humoral and cell-mediated immune responses will be determined in MGUS patients at 4 time-points following vaccination with the influenza virus subunit vaccine for the season 2010-2011, and compared with the responses measured in Multiple Myeloma patients and healthy controls.

Intervention

not applicable

Study burden and risks

You will get the flu shot and are therefore possibly protected against influenza illness, but whether that actually is so is part of this research. In addition, you do not have a direct personal interest in the case of participation in this research. The extra outpatient clinic visit can be an additional burden for you. In addition, there is in total 240 ml of blood to be

drawn.

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

Patients/controls
- (MGUS patients only)patients have to fulfill the diagnostic criteria for MGUS
- serum M protein<30g/L
- Clonal plasma cells in bone marrow <10%
- No myeloma related dysfunction
- No other B-cell proliferative disease
-informed consent;Multiple Myeloma inclusion criteria
- patients who fulfill the diagnostic criteria for multiple myeloma
- Monoclonal plasma cells in bone marrow >10% and/or presence of biopsy proven

plasmacytoma
- Monoclonal protein present in serum and/or urine
-Myeloma related organ dysfunction
o Calcium elevation in the blood S. Calcium >10.5 mg/l or upper limit of normal
o Renal insufficiency: S. Creatinine > 2 mg/dl
o Anemia Hemoglobin < 10 g/dl or 2 g < normal
o Lytic bone lesions or osteoporosis
-Patients with stage 1 myeloma (according to the International Staging System)
o Serum β2-MG* <3.5 mg/L
o Serum albumin >=3.5 g/dl
-Informed consent

Exclusion criteria

MGUS patients/ healthy controls
- age under 18 years
- current infection, defined as fever in combination with clinical focal signs of infection and the need for therapeutic antibiotic treatment
- influenza vaccination within the 6 months prior to the study
- pregnancy
- malignancy
- known allergy to or former severe reaction following Influvac®;Multiple Myeloma Exclusion criteria
- Patients in late stage disease
- Patients who have undergone stem cell transplantation
- current infection, defined as fever in combination with clinical focal signs of infection and the need for therapeutic antibiotic treatment
- pregnancy
- known allergy to or former severe reaction following Influvac®

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-10-2010
Enrollment:	122
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	influenza subunit

Ethics review

Approved WMO Date:	14-09-2010
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	24-09-2010
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
EudraCT	EUCTR2010-022693-14-NL
CCMO	NL33206.042.10