Response to influenza and pneumococcal vaccination in myeloma patients treated with Lenalidomide with/without steroiden.

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To compare the number of responders to vaccination with the influenza virus vaccine and pneumococcal vaccine at different time points in treatment cycle of lenalidomide. Secondly to study the immune-response to vaccination, during treatment with...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Hepatobiliary neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON40484

Source
ToetsingOnline

Brief title
REVIVA

Condition

- Hepatobiliary neoplasms malignant and unspecified
- Plasma cell neoplasms

Synonym
bonemarrow cancer, Multiple myeloma

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W,Crowdfunding

Intervention

Keyword: lenalidomide, myeloma, steroids, vaccination

Outcome measures

Primary outcome

Antibody titres against the influenza virus vaccine and different serotypes of

s.pneumoniae before and after vaccination. Titres will be interpreted and

classified in responder or non-responder.

Secondary outcome

* Immunoglobulin levels and subclasses.

* Lymphocyte subsets (number of B cells T cells, CD3, CD4, CD8 and NK cells).

* Different types of T cells (Th17 cells, regulatory T cells)

* Production of IFN-g by CD4+ cells. This will be measured in order to

investigate if cellular mediated immune responses are intact during

lenalidomide treatment.

* Cytokines (for example interleukin 2 and 6, TNF-* and IFN-g)

* Complement factors

Study description

Background summary

Patients with MM who are treated with lenalidomide with or without steroids or chemotherapy are at risk of developing infections. Vaccination with influenza vaccine and pneumococcal vaccine might protect patients against these pathogens.

In this study the humoral and cellular immune response to vaccination is investigated in patients with multiple myeloma who are treated with lenalidomide with/without steroids or chemotherapy.

Study objective

To compare the number of responders to vaccination with the influenza virus vaccine and pneumococcal vaccine at different time points in treatment cycle of lenalidomide. Secondly to study the immune-response to vaccination, during treatment with lenalidomide with/without steroids and/or chemotherapy in relation to the immunesystem.

Study design

The design is a randomised trial. A control group is established as reference for response to influenzavaccination and for normal values of immune system components which play a role in the pathophysiology of multiple myeloma (to answer the second objective). A total of hundred (100) patients with multiple myeloma, who are treated with lenalidomide with or without steroids/chemotherapy, will be included. Patients will be randomised in 2 groups: the first group will be vaccinated on day 1 of a treatment cycle of lenalidomide (= early group), the second group will be vaccinated on day 20 (= late group). These 2 groups will be compared to each other. The control group will consist of 40 age, sex and co-morbidity matched controls who are recruited at the general practioner.

Intervention

All patients and matched controls will receive the influenza virus vaccine Influvac® or Vaxigrip® which will be used in the authorised form according to existing vaccination protocol for immune compromised patients. Influenza vaccine will be delivered to each participating hospital by the RIVM. Secondly they will receive Prevnar 13, a pneumococcal conjugate vaccine which will be used in the authorised form. At two different time points before and after vaccination sera will be taken and investigated.

Study burden and risks

Patients will be vaccinated with the annual influenza vaccine that is indicated for this patient group according to existing vaccination protocols in immune compromised patients. A second vaccination with a pneumococcal vaccine will be given. Blood samples will be drawn before the vaccination and three weeks after vaccination, so two blood samples will be drawn. If possible, vaccination will be integrated in normal out-patient clinical visits. The vaccines will be used in the authorised form and for the authorised purpose, therefore no additional risks are to be expected. Patient discomfort might consist of a painful arm/leg

after vaccination. Adverse events which are common (0.1-1%) include headache, fever, myalgia, artralgia, nausea, vomiting, and pain and redness at the vaccination spot. Rare events are allergic reactions (very rare leading to shock), angio edema, neurologic disorders and urticaria. Benefit is protection against infection with the influenza virus or infection with s.pneumoniae.

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

1. Patients with multiple myeloma who are treated with lenalidomide with/without steroids.
2. Age > 18 years
3. Signing informed consent.;Control group:
1. Age, sex and co-morbity matched
2. Age >18 years

3. Signing informed consent

Exclusion criteria

1. Fever at time of vaccination
2. Completion of Lenalidomide therapy prior to vaccination
3. previous/known allergic reaction to any of the components of the influenzavaccin given;Control group:
1. Use of immune supressive drugs
2. Fever at time of vaccination
3. Previous/known allergic reaction to any of the components of the influenzavaccin given

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	140
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Influvac or Vaxigrip
Product type:	Medicine
Brand name:	Prevnar 13

Ethics review

Approved WMO Date:	10-07-2014
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	02-09-2014
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	EUCTR2012-005713-39-NL
CCMO	NL42970.100.14
Other	volgt