# Response to influenza virus vaccination in patients immunocompromised due to chemotherapy

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·To compare the serological response to influenza vaccination in mamma carcinoma patients treated with FEC-containing, triweekly regimens at day 4 ( +/- 1 day) of the chemotherapy cyclus with the response to vaccination in otherwise healthy patients...

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| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Viral infectious disorders |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON33424

**Source**
ToetsingOnline

**Brief title**
Rifluvac

### Condition

- Viral infectious disorders
- Breast neoplasms malignant and unspecified (incl nipple)

**Synonym**
breast cancer., Mamma carcinoma

**Research involving**
Human

### Sponsors and support

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

## Intervention

**Keyword:** chemotherapy, influenza, vaccination

## Outcome measures

### Primary outcome

adequate rise in antibody titre against the influenza virus

### Secondary outcome

·Antibody titres against the influenza virus before and after vaccination

# Study description

### Background summary

Patients treated with chemotherapy or immunosuppressives are at higher risk of influenza infection and mortality and morbidity are higher compared to healthy adults. Vaccination against the influenza virus can prevent these complications. Although vaccination in oncology patients is recommended, in the Netherlands, a protocol for vaccination during chemotherapy does not exist. In this study it is investigated whether vaccination during chemotherapy is effective in reaching protective serum antibody concentrations

### Study objective

·To compare the serological response to influenza vaccination in mamma carcinoma patients treated with FEC-containing, triweekly regimens at day 4 ( +/- 1 day) of the chemotherapy cyclus with the response to vaccination in otherwise healthy patients with heart failure (with proven equal rise in antibody titre compared to healthy volunteers).
·To compare the serological response to influenza vaccination in mamma carcinoma patients treated with FEC-containing, triweekly regimens at day 16 ( +/- 1 day) of the chemotherapy cyclus with the response to vaccination in otherwise healthy patients with heart failure (with proven equal rise in antibody titre compared to healthy volunteers).
·To compare the serological response to influenza virus vaccination in mamma carcinoma patients treated with FEC-containing, triweekly regimens on two different moments of vaccination: at day 4 ( +/- 1 day) versus day 16 (+/- 1 day) of the chemotherapy cyclus.

### Study design

The study comprises patients with chemotherapy for mammacarcinoma and a control group of heart failure patients. vaccination will be measured in mamma carcinoma patients, randomised for early or late vaccination. The early group will be vaccinated at day 4 +/- 1 day of the chemotherapy cycle, the late group at day 16 +/- 1 day of the chemotherapy cycle. All responses will be compared to the response in heart failure patients.

### Intervention

The influenza virus vaccine is given in the period October/November 2009

### Study burden and risks

Adverse effects to vaccination in oncology patients overall are mild. in general, side-effects of influenza vaccination are soreness at the injection site and, less commonly, fever, malaise, myalgia, arthralgia, or both, starting 6-12 h after vaccination and lasting less than 48 h. The risk of venapunction consists of a haematoma on the injection site. In conclusion, it is expected that the risks of the immunisation are small, whereas considerable morbidity can be prevented by vaccination.

## 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 mamma carcinoma treated with FEC-containing triweekly chemotherapy at moment of vaccination
2.Patients with heart failure and therefore having an indication for the influenza vaccination
3.Age >= 18 years
4.Signing of informed consent

### Exclusion criteria

1.Fever at time of vaccination defined as a temperature of >= 38.5 °C.
2.Previous/known allergic reaction to any of the components of the vaccines given, for example hypersensitivity to egg protein
3.Thrombocytopenia (defined as < 50 x 10*9/L ) at moment of vaccination
4.Treatment with prednisolone on moment of vaccination.

## Study design

### Design

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

## Recruitment

NL

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| Recruitment status: | Recruiting |
| Start date (anticipated): | 08-10-2009 |
| Enrollment: | 385 |
| Type: | Actual |

# Ethics review

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| Approved WMO Date: | 27-07-2009 |
| Application type: | First submission |
| Review commission: | CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag) |
| Approved WMO Date: | 24-09-2009 |
| Application type: | First submission |
| Review commission: | CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag) |
| Approved WMO Date: | 28-09-2009 |
| Application type: | Amendment |
| Review commission: | CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag) |
| Approved WMO Date: | 08-10-2009 |
| Application type: | Amendment |
| Review commission: | CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag) |
| Approved WMO Date: | 27-10-2009 |
| Application type: | Amendment |
| Review commission: | CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag) |
| Approved WMO Date: | 16-11-2009 |

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| Application type: | Amendment |
| Review commission: | CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag) |

# 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 | EUCTR2009-014340-11-NL |
| CCMO | NL28941.000.09 |