

# MBL and prediction of risk on chemotherapy induced febrile neutropenia in patients with a solid tumor.

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To explore the association between MBL level at baseline and the incidence of febrile neutropenia.

|                              |                                |
|------------------------------|--------------------------------|
| <b>Ethical review</b>        | Approved WMO                   |
| <b>Status</b>                | Recruitment stopped            |
| <b>Health condition type</b> | Bacterial infectious disorders |
| <b>Study type</b>            | Observational invasive         |

## Summary

### ID

NL-OMON35673

### Source

ToetsingOnline

### Brief title

MBL and febrile neutropenia

### Condition

- Bacterial infectious disorders
- Miscellaneous and site unspecified neoplasms malignant and unspecified

### Synonym

febrile neutropenia, fever after chemotherapy

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Sint Franciscus Gasthuis

**Source(s) of monetary or material Support:** Amgen, intern onderzoeks-stichting

## **Intervention**

**Keyword:** chemotherapy, Febrile neutropenia, MBL, solid tumors

## **Outcome measures**

### **Primary outcome**

To explore the association between MBL level at baseline and the incidence of febrile neutropenia.

### **Secondary outcome**

To explore the prognostic value of MBL-genotype on the incidence and severity of febrile neutropenia

To explore whether the MBL level is different prior to chemotherapy cycle 2 compared to baseline.

To explore the association between MBL level at baseline and the severity of febrile neutropenia during the first course

To explore the association between MBL level at baseline and the incidence and severity of febrile neutropenia during the first 2 courses

To explore the association between MBL level at baseline and the incidence and severity of febrile neutropenia during the treatment period

To explore the association between MBL level before the second course and the incidence and severity of febrile neutropenia during the 2nd course

To describe the change in MBL levels during a FN episode.

To explore the potential change in MBL levels during a FN episode to severity of FN.

## Study description

### Background summary

Febrile neutropenia is a threatening complication of chemotherapy. Assessment of the risk of suffering from febrile neutropenia, before the initiation of chemotherapy is important

### Study objective

To explore the association between MBL level at baseline and the incidence of febrile neutropenia.

### Study design

cohort study

### Study burden and risks

collection of 20 ml extra blood

## Contacts

### Public

Sint Franciscus Gasthuis

Kleiweg 500  
3045PM  
NL

### Scientific

Sint Franciscus Gasthuis

Kleiweg 500  
3045PM  
NL

## Trial sites

## Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

Treatment with chemotherapy for solid malignancy

### Exclusion criteria

Treatment with growth factor support and/or antibiotics

## 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): 12-05-2012

Enrollment: 243

Type: Actual

## Ethics review

Approved WMO

Date: 15-02-2012

Application type: First submission

Review commission: RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

## 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     | NL37499.099.11 |