

# MBL(Mannose binding lectine)-studie.

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruiting
<b>Health condition type</b>	-
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON24964

### Source

Nationaal Trial Register

### Health condition

Patients treated with chemotherapy for a solid tumor

Patienten die behandeling krijgen met chemotherapie vanwege een solide tumor

## Sponsors and support

**Primary sponsor:** Sint Franciscus Gasthuis

**Source(s) of monetary or material Support:** Amgen, Roche

## Intervention

## Outcome measures

### Primary outcome

Relation between baseline MBL and incidence of febrile neutropenia (FN).

### Secondary outcome

1. MBL genotype and relation FN;
2. Changes in MBL concentration;

3. Relate severity of FN with MBL levels.

## Study description

### Background summary

Measuring MBL prior to chemotherapy and at an episode of FN in patients receiving chemotherapy for a solid tumor.

### Study objective

MBL deficiency might give rise to a higher chance of the occurrence of febrile neutropenia.

### Study design

Prior to cycle 1 and prior to cycle 2 and during FN measurement of MBL.

### Intervention

N/A

## Contacts

### Public

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### Scientific

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## Eligibility criteria

## Inclusion criteria

1. Patients commencing chemotherapy treatments for a solid tumor;
2. Written informed consent.

## Exclusion criteria

1. Previous participation in the current study;
2. Patients < 18 yrs;
3. Patients not able to give informed consent;
4. Patients receiving chemotherapy in a weekly schedule or a bi-weekly dose dense schedule;
5. Patients receiving granulocyte growth factor support (G-CSF);
6. Patients receiving a treatment with an individualized risk (combination of scheme and presence of risk factors) on FN over 20% according to the EORTC guidelines;
7. Patients receiving (prophylactic) antibiotics;
8. Patients receiving concomittant radiotherapy.

## Study design

### Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

### Recruitment

NL	
Recruitment status:	Recruiting

Start date (anticipated):	01-03-2012
Enrollment:	243
Type:	Anticipated

## Ethics review

Positive opinion	
Date:	03-04-2012
Application type:	First submission

## 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
NTR-new	NL3246
NTR-old	NTR3398
Other	SFG : 2011/42
ISRCTN	ISRCTN wordt niet meer aangevraagd.

## Study results

### Summary results

N/A