# Monclonal B-cell Lymphocytosis; clinical and biological characteristics

Published: 27-12-2010 Last updated: 03-05-2024

To investigate the clinical and biological characteristics of MBL in order to obtain insight into CLL leukemogenesis and disease progression.

Ethical review	Not approved	
Status	Will not start	
Health condition type	Leukaemias	
Study type	Observational non invasive	

# **Summary**

### ID

NL-OMON34393

**Source** ToetsingOnline

Brief title Monoclonal B-cell Lymphocytosis

# Condition

Leukaemias

**Synonym** chronic leukemia, Monoclonal B-cell Lymphocytosis

#### **Research involving** Human

## **Sponsors and support**

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

### Intervention

Keyword: Apoptosis, MBL, Monoclonal B-cell Lymphocytosis, T-cell subsets

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### **Outcome measures**

#### **Primary outcome**

- Characterisation of cell surface markers of MBL patients compared to an

age-matched control group from general population and to CLL patients.

- Gene expression levels of MBL patients compared to normal B-lymphocytes and to CLL patients.

#### Secondary outcome

- Descriptive analysis of incidence of infections and antibiotics usage in

patients with MBL.

- Characterisation of cell surface markers of non-progressive MBL patients

versus progressive MBL patients

- Characterisation of gene expression levels of non-progressive MBL patients

versus progressive MBL patients.

# **Study description**

#### **Background summary**

Monoclonal B-cell Lymphocytosis (MBL) is a relatively new and asymptomatic entity wherein small B cell clones, with a typical Chronic Lymphocytic Leukaemia (CLL)-immunophenotype, are detectable in the peripheral blood. MBL has been shown to be a precursor state for CLL, 15% will develop progressive CLL, 7% eventually require chemotherapy and 2% will die as a result of progressive disease. Since MBL and CLL are characterised by an extremely heterogeneous clinical course, ranging from an indolent disease without progression towards progressive disease requiring treatment and possibly death,

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prognostic markers which can reliably predict the course of the disease at diagnosis are warranted. MBL is of interest to investigate clinical and biological characteristics to better understand the mechanisms of CLL leukemogenesis by identifying factors that are either shared or divergent between MBL and CLL. These clinical and biological characteristics will not only provide inside into the pathophysiology of the disease but also give important information about the prognosis and might enable more sophisticated and individualized new therapeutic strategies.

#### **Study objective**

To investigate the clinical and biological characteristics of MBL in order to obtain insight into CLL leukemogenesis and disease progression.

#### Study design

The study is an observational study in which patients need to visit the hospital once to let drawn blood to investigate T-cell subsets and expression levels of apoptosis genes.

#### Study burden and risks

The risks are low and patients have a minimum of discomfort. Patients only have to visit the hospital once to let drawn blood. This procedure does not interfere with standard medical care and this study will give more insight in CLL leukomegenesis which might benefit CLL patients in future.

# 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**

All patients over the age of 18 years who were diagnosed with MBL or CLL ever since March 2001 are eligible for the study.

# **Exclusion criteria**

Psychiatric disease or inability to give informed consent

# Study design

## Design

Primary purpose: Basic science		
Masking:	Open (masking not used)	
Allocation:	Non-randomized controlled trial	
Intervention model:	Other	
Study type:	Observational non invasive	

### Recruitment

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NL	
Recruitment status:	Will not start
Enrollment:	40

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Type:

Anticipated

# **Ethics review**

Not approved Date: Application type: Review commission:

27-12-2010 First submission 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 CCMO ID NL34627.100.10