# Methionin-low diet in acute leukemia patients, a phase I pilot

Published: 27-05-2020
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Safety of a methionine-low diet in patients with AML

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|---|---|
| **Ethical review** | Not approved |
| **Status** | Will not start |
| **Health condition type** | Leukaemias |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON49508

**Source**
ToetsingOnline

**Brief title**
Methionin-low diet in acute leukemia patients

### Condition

- Leukaemias

**Synonym**
Acute leukemia, blood cancer

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Groningen
**Source(s) of monetary or material Support:** stichting hemato onco

### Intervention

**Keyword:** Diet, Leukemia, Methionin, Restriction

## Outcome measures

### Primary outcome

The safety will be analysed by the occurrence of (S)AE

### Secondary outcome

The effectiveness will be measured in the level of leukaemia blasts and the

methionine-levels in plasma.

# Study description

### Background summary

Leukemia cells have an increased need for methionine. Depletion of methionine in vitro is toxic to leukemia cells but not to healthy cells. Previous phase I and II studies show little to no side effects from a lmethionin-low diet in humans. In this study, we aim to explore the safety and effectiveness of a methionine-low diet in patients with AML

### Study objective

Safety of a methionine-low diet in patients with AML

### Study design

Human experimental study (fase 1 pilot)

### Intervention

A Methionine-low diet, first by tubefeeding, alter by regulare oral foodproducts

### Study burden and risks

Aspiration pneumonia in tube feeding
Bleeding and pain from bone marrow puncture and blood sampling
Weight loss and malnutrition
Limitation in own diet

# Contacts

**Public**
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**Scientific**
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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adults (18-64 years)
Elderly (65 years and older)

## Inclusion criteria

Acute myeloid leukemia
Adult

## Exclusion criteria

Acute promyolocytic leukemia
medical indication for other diet

# Study design

## Design

**Study type:** Interventional

| | |
|---|---|
| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Treatment |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Will not start |
| Enrollment: | 5 |
| Type: | Anticipated |

# Ethics review

Not approved

| | |
|---|---|
| Date: | 27-05-2020 |
| Application type: | First submission |
| Review commission: | METC Universitair Medisch Centrum Groningen (Groningen) |

# 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 | NL73144.042.20 |