Minimal residual disease in peripheral blood compared to bone marrow in patients treated for acute myeloid leukemia

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON25015

Source
NTR

Brief title
MRDPB

Health condition

Acute myeloid leukemia

Sponsors and support

Primary sponsor: None
Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

The primary outcome measure is the prognostic value of (LSC) MRD in PB compared to BM for

relapse free survival (RFS) and overall survival (OS).

Secondary outcome

Secondary outcome is to determine the correlation between MRD in PB and BM and determine the influence of dilution by comparing MRD percentage between the different BM tubes taken from one puncture and the PB sample.

Study description

Background summary

We aim to determine and compare MRD in BM and PB with our current qualified MRD test. The study takes place at the Amsterdam UMC location VUmc and AMC. We take two extra tubes (14 ml total) of heparin blood at the same day as the planned BM sample in AML patients. We will also examine the correlation between the two samples. Moreover, we will examine the influence of hemodilution by numbering the BM collection tubes. We expect to find a lower sensitivity, which may be counterbalanced by an increase in specificity in PB, making it still relevant for prediction of relapse.

Study objective

We expect to find a lower sensitivity, which may be counterbalanced by an increase in specificity in PB, making it still relevant for prediction of relapse.

Study design

At least one

Contacts

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Eligibility criteria

Inclusion criteria

Patient with:
- a diagnosis of AML and related precursor neoplasms according to WHO 2008 classification (excluding acute promyelocytic leukemia) including secondary AML (after an antecedent hematological disease (e.g. MDS) and therapy-related AML), or
- acute leukemia’s of ambiguous lineage according to WHO 2008 or
- a diagnosis of refractory anemia with excess of blasts (MDS) and IPSS-R score > 4.5.
Treated according to HOVON clinical trials with intensive chemotherapy;
Age 18 yr or older;
A bone marrow aspiration has been scheduled;
WHO performance status 0, 1 or 2;
Written informed consent.

Exclusion criteria

Pregnant or lactating females;
Unwilling or not capable to use effective means of birth control.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-08-2021
Enrollment:	151

Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion Date:	25-08-2021
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	NL9690
Other	METC VUmc : METC2021.0021

Study results