Bone marrow evaluation in patients with leukemia and myelodysplasia

Published: 06-02-2014
Last updated: 25-04-2024

The present study will be focused to define the underlying mechanism of resistance in the malignant cells by analyzing the process of proliferation and differentiation in conjunction with the gene profiling and definition of new molecular markers.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Leukaemias
Study type	Observational non invasive

Summary

ID

NL-OMON38969

Source
ToetsingOnline

Brief title
Bone marrow evaluation in AML/MDS

Condition

- Leukaemias

Synonym
acute myeloid leukemia

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Bone marrow - leukemia

Outcome measures

Primary outcome

- Cellular proliferation and differentiation

- Gene profiling studies

- Molecular markers

Secondary outcome

not applicable

Study description

Background summary

Patients treated for leukemia and myelodysplasia have still an unfavorable prognosis despite treatment with intensive chemotherapy and allogenic stem cell transplantation. These results are in general not related to the incapability to treat the patients with chemotherapy but due to the fact that the malignant cells re-emerge 6 - 12 months after cessation of therapy. These findings indicate that the malignant cells, at least a small subpopulation of them, are intrinsic resistant to the applied therapeutic modalities. Further knowledge regarding the underlying mechanisms of resistance might be highly relevant for further improvements in treatment results for these patients. Especially additional information of the cellular and molecular mechanism that operate in these resistant cells.

Study objective

The present study will be focused to define the underlying mechanism of resistance in the malignant cells by analyzing the process of proliferation and differentiation in conjunction with the gene profiling and definition of new molecular markers.

Study design

In patients diagnosed with AML or MDS additional bone marrow cells (20 ml) will

be collected during the standard diagnostic bone marrow test.

Study burden and risks

At the standard procedure of diagnostic bone marrow punction 20 ml extra marrow is drawn. This increases the procedure with 2 minutes. There are no additional punctions done.

Contacts

Public
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9713 GZ
NL
Scientific
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9713 GZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

AML/MDS patients undergoing a diagnostic bone marrow-biopsy

Exclusion criteria

Age < 18 years

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-06-2014
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO Date:	06-02-2014
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	31-12-2015
Application type:	Amendment
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	NL43844.042.13