Dose-reduced versus standard conditioning followed by allogeneic stem cell Transplantation in patients with MDS or sAML: A randomised phase III study

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The present study will be a multicenter, prospective phase III-study comparing dose-reduced versus standard conditioning followed by allogeneic stem cell transplantation from related or unrelated donors in patients with MDS or secondary AML.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Leukaemias
Study type	Interventional

Summary

ID

NL-OMON31335

Source
ToetsingOnline

Brief title
alloRIC in MDS

Condition

- Leukaemias

Synonym
Myelodysplastic Syndrome and secondairy Acute Myeloid Leukaemia

Research involving
Human

Sponsors and support

Primary sponsor: European Group for Blood and Marrow Transplantation (EBMT) tav Prof.

Dr. T. de Witte
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Allogeneic Stem Cell Transplantation, MDS, Reduced Intensity Conditioning

Outcome measures

Primary outcome

The hypothesis is that a dose-reduced conditioning will reduce the non-relapse mortality from 40 % to 20 % at one year after allogeneic stem cell transplantation.

Secondary outcome

Comparison of haematopoietic recovery by day +30 post transplant between two arms.

* Comparison of toxicity of both regimens.

* Incidence of acute GVHD by day +100 and of chronic GVHD by day +365.

* Overall survival and event-free survival post-transplant at two years.

* Incidence of relapse post-transplant at two years.

* Comparison of VOD (veno-occlusive disease0 between the two arms.

* Comparison of infectious complications at one year and at two years after transplantation.

* Comparison of quality of life between the treatment arms.

Study description

Background summary

Myelodysplastic syndromes (MDS) are a heterogeneous group of clonal

haematological disorders, which are characterised by abnormal cellular maturation resulting in cytopenias and a variable risk of progression to acute leukaemia.
Currently allogeneic stem cell transplantation has been shown the most effective treatment. However this treatment is accompanied by high treatment related mortality. Recently, reduced intensity allogeneic stem cell transplantation has been developed for patients with hematological malignancies. However this treatment is especially employed in older patients and in patients who are due to comorbidity, not eligible for allogeneic stem cell transplantation after standard conditioning. Comparable studies are not available yet

Study objective

The present study will be a multicenter, prospective phase III-study comparing dose-reduced versus standard conditioning followed by allogeneic stem cell transplantation from related or unrelated donors in patients with MDS or secondary AML.

Study design

Prospective randomised phase III multi-center study.

Intervention

Arm A (standard conditioning):
Busulfan 4 mg/kg/day orally during 4 days or Busilvex 3.2 mg/kg/day intravenously. during 4 days.
Cyclophosphamide 60 mg/kg/day intravenously during 2 days

Arm B (reduced intensity conditioning)
Busulfan 4 mg/kg/day orally during 2 days or Busilvex 3.2 mg/kg/day intravenously during 2 days.
Fludarabine 30 mg/m2/day intravenously during 5 days

Study burden and risks

The therapy strategies to be checked in this protocol have * in short * the following advantages and disadvantages:

Standard-Conditioning (Arm A):
* Advantage: Because of the intensity of the chemotherapy, less relapses after allogeneic
transplantation are probably to be expected.
* Disadvantage: Due to the intensity of the chemotherapy, more therapy-related complications, especially a higher number of treatment-related mortality, are

probable.

Dose-reduced Conditioning (Arm B):
* Advantage: Because of the less intensive chemotherapy, less therapy-related side effects and a lower risk of therapy-related mortality are probable.
* Disadvantage: Maybe a higher relapse rate due to the lower intensity of the chemotherapy.

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

Cytogenetically proven MDS or sAML
Patient between 18 and 60 years of age in case of a HLA matched unrelated donor

Patient between 50 and 65 years of age in case of a HLA matched related donor

Exclusion criteria

Blasts >20% in bone marrow at time of transplantation
Patients with a life-expectancy of less than six months because of another debilitating disease
Invasive fungal infection at time of registration

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Start date (anticipated):	01-09-2007
Enrollment:	10
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL18050.091.07