



Trial Description

Title

Prognostic value and development of psycho-social factors and functional aspects in elderly patients with higher risk MDS and AML. A multi-center observational study.

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

Joint decision-making resulting in the individually best treatment option (especially regarding treatment intensity) is one of the most difficult tasks in the care of elderly leukemia patients. Objective patient-specific parameters that can facilitate this process have not been sufficiently investigated. It is essential to obtain solid knowledge on subjective quality of life, functional reserves and psychological distress of the affected patients. Our aim is to validate previous data on a Comprehensive Geriatric and Quality of Life Assessment in 500 patients with higher risk MDS and AML in a prospective multic-center observational study.

Brief Summary in Scientific Language

Prospective prognostic factor study for elderly leukemia patients based on results of a comprehensive geriatric and quality of life assessment.

Do you plan to share individual participant data with other researchers?

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00003601**
- Date of Registration in DRKS: **2012/04/13**
- Date of Registration in Partner Registry or other Primary Registry: [---]*
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**



DRKS-ID: **DRKS00003601**

Date of Registration in DRKS: **2012/04/13**

Date of Registration in Partner Registry or other Primary Registry: [---]*

Investigator Sponsored/Initiated Trial (IST/IIT): **yes**

Ethics Approval/Approval of the Ethics Committee: **Approved**

- (leading) Ethics Committee Nr.: **122/12 , Ethik-Kommission der Albert-Ludwigs-Universität Freiburg**

Secondary IDs

Health condition or Problem studied

- ICD10: **C92.0 - Acute myeloid leukaemia**
- ICD10: **D46 - Myelodysplastic syndromes**

Interventions/Observational Groups

- Arm 1: **Patients with MDS/AML will be asked to undergo a geriatric and quality of life assessment prior to treatment initiation and every three months thereafter for one year.**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **Single arm study**
- Blinding: [---]*
- Who is blinded: [---]*
- Control: **Uncontrolled/Single arm**
- Purpose: **Prognosis**
- Assignment: **Single (group)**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Overall survival within a 2.5 year observation period. Components of a comprehensive geriatric assessment will be evaluated for their prognostic value.

Secondary Outcome

Independence (Barthel Index), Quality of Life (EORTC QLQ C 30), psychological distress (HADS) prior to treatment initiation, and every 3 months for 1 year.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2012/04/16**
- Target Sample Size: **500**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **60 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

Higher risk MDS/AML, age \geq 60 years, written informed consent, anticipated compliance and geographic proximity for follow-up assessments

Exclusion criteria

other malignant diseases not in remission, impaired mental status with inability to fill out questionnaires and to obey simple demands. Trial participation for medical therapy is NOT an exclusion criterion

Addresses

■ **Primary Sponsor**

Medizinische Universitätsklinik Freiburg
Mr. Prof. Dr. med. Michael Luebert
Hugstetter Str. 55
79106 Freiburg
Germany

Telephone: **0761 270 32790**

Fax: [---]*

E-mail: [---]*

URL: [---]*

■ **Contact for Scientific Queries**

Universitätsklinik Freiburg, Med. Klinik
Abteilung Hämatologie/ Onkologie
Mr. Prof. Dr. med. Michael Luebbert
Hugstetter Strasse 55
79106 Freiburg
Germany

Telephone: **0761-270-32790**

Fax: **0761-270-36970**

E-mail: **michael.luebbert at uniklinik-freiburg.de**

URL: [---]*

■ **Contact for Public Queries**

Universitätsklinikum Freiburg, Abt. Med. 1
Hämatologie / Onkologie
Mr. Prof. Dr. med. Michael Luebbert
Hugstetter Strasse 55
79106 Freiburg
Germany

Telephone: **0761 270 32790**

Fax: **0761 270 36970**

E-mail: **michael.luebbert at uniklinik-freiburg.de**

URL: [---]*

Sources of Monetary or Material Support

■ **Private sponsorship (foundations, study societies, etc.)**

José Carreras Leukämie-Stiftung
Elisabethstraße 23
80796 München
Germany

DRKS-ID: **DRKS00003601**

Date of Registration in DRKS: **2012/04/13**

Date of Registration in Partner Registry or other Primary Registry: [---]*

Private sponsorship (foundations, study societies, etc.)

José Carreras Leukämie-Stiftung

Elisabethstraße 23

80796 München

Germany

Telephone: **089 / 272 904-0**

Fax: **089 / 272 904-44**

E-mail: [---]*

URL: [---]*

Status

- Recruitment Status: **Recruiting ongoing**
- Study Closing (LPLV): [---]*

Trial Publications, Results and other documents

* This entry means the parameter is not applicable or has not been set.

*** This entry means that data is not displayed due to insufficient data privacy clearing.