Public Title	Lenalidomide Maintenance Therapy in Patients With MDS or AML
Scientific Title	Lenalidomide Maintenance Therapy in Patients With MDS or AML With Cytogenetic Abnormalities Involving Monosomy 5 or del5q After Allogeneic Hematopoietic Stem Cell Transplantation (HSCT)
Short Title	LENAMAINT
Id KN/ELN	LN_DEUTSC_2009_331
Trialgoup	Deutsche MDS
Type of Trial	multicentric, open-label
Phase	Phase I/II
Disease	Acute myeloid leukemia(AML) AML all subtypes without FAB M3
Stage of Disease	.
Aim	- To determine whether lenalidomide maintenance therapy in MDS or AML patients with monosomy 5 or del5q abnormalities after allogeneic HSCT can result in a relapse rate </= 50%. - Determine the safety of lenalidomide when given after allogeneic HSCT.
Outcomes	- • Cumulative incidence of relapse rate at 1 year post transplantation (Primary Outcome) - • Overall survival 1 year post transplantation - • Incidence and severity of acute and chronic GVHD 1 year post transplantation - • Safety (type, frequency, severity and relationship of adverse events to study treatment)
Inclusion Criteria	- 1. Understand and voluntarily sign an informed consent form. - 2. Age >/=18 years at the time of signing the informed consent form. - 3. Able to adhere to the study visit schedule and other protocol requirements. - 4. AML (>/= 20% blasts) including secondary (s)AML (after radio-chemotherapy) with karyotype abnormalities involving monosomy 5 or del5q or - MDS and sMDS RAEB-1 and RAEB-2 with karyotype abnormalities involving monosomy 5 or del5q or - MDS and sMDS type RA(+/-RS) or RCMD(+/-RS) only with complex karyotype abnormalities involving monosomy 5 or del5q - 5. in complete hematological remission documented by bone marrow aspiration within 8-12 weeks after allogeneic HSCT - 6. All previous cancer therapy, including radiation, hormonal therapy and surgery, must have been discontinued at least 4 weeks prior to treatment in this study. - 7. ECOG performance status of </= 2 at study entry (see Appendix I). - 8. Laboratory test results within these ranges: - Absolute neutrophil count >/= 1.0 x 10^9/L - Platelet count >/= 100 x 10^9/L - Serum creatinine </= 2.0 mg/dL - Total bilirubin </= 1.5 mg/dL - AST (SGOT) and ALT (SGPT) </= 5 x ULN

- 9. Females of childbearing potential (FCBP)† must agree to use two reliable forms of contraception simultaneously or to practice complete abstinence from heterosexual intercourse during the following time periods related to this study: 1) for at least 28 days before starting study drug; 2) while participating in the study; and 3) for at least 28 days after discontinuation from the study. The two methods of reliable contraception must include one highly effective method (i.e. intrauterine device (IUD), hormonal [birth control pills, injections, or implants], tubal ligation, partner's vasectomy) and one additional effective (barrier) method (i.e. latex condom, diaphragm, cervical cap). FCBP must be referred to a qualified provider of contraceptive methods if needed.

Exclusion Criteria

- 1. Any serious medical condition, laboratory abnormality, or psychiatric illness that would prevent the subject from signing the informed consent form.
- 2. active uncontrolled acute GVHD overall grade 3-4
- 3. Pregnant or breast feeding females. (Lactating females must agree not to breast feed while taking lenalidomide).
- 4. History of arterial or venous embolism or stroke
- 5. Any condition, including the presence of laboratory abnormalities, which places the subject at unacceptable risk if he/she were to participate in the study or confounds the ability to interpret data from the study.
- 6. Use of any other experimental drug or therapy to treat MDS or AML within 28 days of baseline (patients within a clinical trial evaluating new conditioning regimens are allowed to participate in the LENAMAINT study)
- 7. Known hypersensitivity to thalidomide or lenalidomide.
- 8. history of erythema nodosum if characterized by a desquamating rash while taking thalidomide or similar drugs.
- 9. Known positive for HIV or infectious hepatitis, type A, B or C.
- † A female of childbearing potential is a sexually mature woman who: 1) has not undergone a hysterectomy or bilateral oophorectomy; or 2) has not been naturally postmenopausal for at least 24 consecutive months (i.e., has had menses at any time in the preceding 24 consecutive months).

Age >= 18 years

Status Closed

start of Recruitment 01.01.2009

Recruiting countries Germany

Target Sample Size 50

Leader

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Centre of Trial	Universitätsklinikum Carl Gustav Carus, Dresden
Diagnostics	**gene expression** Hämatologisches Labor, Universitätsklinikum Dresden
Sponsors	TU Dresden (Dresden University of Technology; Study Alliance Leukemia (SAL) / Studienzentrale) (Main Sponsor)
Other Registers	ClinicalTrials.govNCT00720850
Interventions	- Lenalidomide will be supplied as 5 mg and 10 mg capsules for oral administration.
Therapy	Lenalidomide will be supplied as 5 mg and 10 mg capsules for oral administration. The planned dose of lenalidomide for investigation is 10 mg/day, orally for 21 days with 7 days rest (28 day cycle) for a total of 12 cycles. Dosing will be in the morning at approximately the same time each day.
Remark	- MDS IPSS INT-2/HIGH und AML in CR - Del5q - in CR after Tx