European LeukemiaNet
SHORTPROTOCOL
MDS 5-azacitidine (Vidaza)

Scientific Title	Treatment of imminent haematological relapse in patients with AML and MDS following allogeneic stem cell transplantation with 5-azacitidine (Vidaza®)
Short Title	MDS 5-azacitidine (Vidaza)
Id KN/ELN	LN_NN_2006_214
Trialgoup	NN
Type of Trial	prospective, open-label, pilot study
Phase	Phase II
Disease	Stem cell transplantation(SCT) AML Acute myeloid leukemia(AML) Stem cell transplantation Stem cell transplantation(SCT) MDS Myelodysplastic Syndrome(MDS) Stem cell transplantation
Stage of Disease	relapsed/refractory
Aim	- Investigation of the efficacy of 5-azacitidine in preventing haematological relapse in patients with CD34+ AML or MDS and decreasing CD34 chimerism following allogeneic HSCT - Investigation of the efficacy of 5-azacitidine over a follow-up period of 6 months after the last cycle - Investigation of the tolerability of 5-azacitidine post-allogeneic HSCT (visit 2.1 to visit 3)
Outcomes	- Rise in CD34 chimerism > 80% 3 months after the last of 4 cycles of 5-azacitidine (Primary Outcome) - Rise in CD34 chimerism > 80% 6 months after the final cycle - name Incidence of infectious complications or toxicity during therapy with 5-azacitidine: allergy, hepatic toxicity (ASAT, bilirubin), renal toxicity creatinine), acute gastrointestinal toxicity (nausea, diarrhoea) and haematological toxicity (leukopenia, anaemia, thrombopenia) (visit 2.1 to visit 3)
Inclusion Criteria	- Age > 18 years - Patients with CD34+ AML or MDS post-allogeneic HSCT - Written patient consent after consultation - Leukocytes > 3 Gpt/l and platelets > 75 Gpt/l (transfusion-independent) - AML/MDS: donor chimerism less than 80% in the CD34+ subpopulation following allogeneic HSCT in patients with CD34+ AML or MDS, but with no haematological relapse (blasts less than 5% in bone marrow)
Exclusion Criteria	- Known intolerance to 5-azacitidine or mannitol - Uncontrollable infectious disease - Patients with active hepatitis B or C or HIV infection - Severe hepatic function impairment (ASAT and ALAT may not be above three times the normal value) or hepatic cirrhosis, or malignant hepatic tumour - Renal function impairment (creatinine greater than twice the normal value, creatinine clearance less than 50 ml/min) - Pregnancy or lactation - Women of childbearing age, except for those who meet the following criteria: - postmenopausal (12 months natural amenorrhoea) - postoperative (6 weeks after bilateral ovarectomy with or without hysterectomy)

- regular and correct use of a contraceptive method with an error rate less than 1% per year (e.g. implants, depot injections, combined oral contraceptives, intrauterine device – IUD, whereby hormonal coils with a Pearl Index of less than 1% are safer than copper coils)
- sexual abstinence
- Partner vasectomy
- Men who do not use one of the following for contraception:
- sexual abstinence
- post vasectomy
- condoms
- Participation of the patient in a drug trial outside the indication of allogeneic transplantation up to four weeks before study initiation
- Addictive or other illnesses that prevent the person concerned from comprehending the nature and impact, as well as potentical consequences of the clinical trial
- Evidence that the patient may intentionally not comply with the protocol, e.g. lack of cooperation

Age	>= 18 years
Status	Closed
start of Recruitment	19.10.2006
Recruiting countries	Germany
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Centre of Trial	Universitätsklinikum Carl Gustav Carus, Dresden
Other Registers	ClinicalTrials.govNCT00422890 (Primary Register) European Clinical Trials Database - EUDRACT2006-001040-31
Remark	Inclusion only for patients with CD34 pos. AML or MDS