Kompetenznetz "Akute und chronische Leukämien"

KURZPROTOKOLL

ONO 1910

Öffentlicher Titel	Randomisierte Studie zu ON 01910.Na in refraktärer MDS mit Blastenexzess
Wissenschaftl. Titel	Phase III MultiCenter Randomized Controlled Study to Assess Efficacy and Safety of ON 01910.Na 72-Hr Continuous IV Infusion in MDS Patients With Excess Blasts Relapsing After or Refractory to or Intolerant to Azacitidine or Decitabine
Kurztitel	ONO 1910
Studiennummer KN/ELN	LN_NN_2010_473
Studiengruppe	NN
Studienart	multizentrisch, randomisiert, offen
Studienphase	Phase III
Erkrankung	Myelodysplastisches Syndrom (MDS) - Intermediär II und Hochrisiko
Leukämiestadium	.
Ziele	- Overall survival - Overall response (complete and partial remission) according to 2006 IWG criteria - Complete bone marrow response according to 2006 IWG criteria - Hematological improvements according to 2006 IWG criteria - Scores of Quality of Life Questionnaire - Adverse events - Change in Aneuploidy - Transition time to AML - Incidence of infections and bleeding episodes.
Einschlusskriterien	- MDS diagnosis confirmed within 6 weeks prior to entry according to WHO or FAB classification - MDS classified as follows, according to WHO and FAB classification: - a. RAEB-1 (5% - 9% BM blasts) - b. RAEB-2 (10% - 20% BM blasts) - c. CMML (10% - 20% BM blasts) and WBC < 13,000/L - d. RAEB-t (21% - 30% BM blasts), with following criteria: - aa. WBC < 25 x 10E9/L at entry - bb. Stable WBC at least 4 weeks prior to entry and not requiring intervention for WBC control with hydroxyurea, chemotherapy, or leukopheresis. - At least one cytopenia (ANC < 1800/µL or platelet count < 100,000/µL or hemoglobin <10 g/dL) - Progression according to 2006 International Working Group (IWG) criteria any time after start of azacitidine or decitabine during past 2 years; or failure to achieve complete or partial response or hematological improvement (according to 2006 IWG) after at least six 4-week cycles of azacitidine or four 6-week cycles of decitabine during past 2 years; or relapse after initial complete or partial response or hematological improvement (according to 2006 IWG criteria) observed after at least six 4-week cycles of azacitidine or four 6-week cycles of decitabine during past 2 years; or, intolerance to azacitidine or decitabine defined by drug-related Grade 3 liver or renal toxicity leading to discontinuation during the past 2 years. - Did not respond to, relapsed after, not eligible for, or opted not to do bone marrow transplantation - Off other MDS treatments for at least 4 weeks; Filgrastim (G-CSF) and erythropoietin allowed before and during the study as clinically indicated. - No need for induction chemotherapy - ECOG status 0, 1 or 2

- Willing to adhere to protocol prohibitions and restrictions
- Patient (or a legally authorized representative) must sign informed consent form to indicate patient's understanding study's purpose and procedures and willingness to participate

Ausschlusskriterien

- Anemia due to factors other than MDS (including hemolysis or gastrointestinal bleeding) unless stabilized for 1 week after RBC transfusion.
- Any active malignancy within the past year, except basal cell or squamous cell skin cancer or carcinoma in situ of the cervix or breast
- Uncontrolled intercurrent illness including, but not limited to, symptomatic congestive heart failure, unstable angina pectoris, or cardiac arrhythmia
- Active infection not adequately responding to appropriate therapy
- Total bilirubin >=1.5 mg/dL not related to hemolysis or Gilbert's disease.
- Alanine transaminase (ALT)/aspartate transaminase (AST) >= 2.5 x upper limit of normal (ULN)
- Serum creatinine >= 2.0 mg/dL
- Ascites requiring active medical management including paracentesis, or hyponatremia (defined as serum sodium value of <130 mEq/L)
- Pregnant or lactating females
- Patients unwilling to follow strict contraception requirements (including condom use for males with sexual partners, and for females: prescription oral contraceptives [birth control pills], contraceptive injections, intrauterine device, double-barrier method [spermicidal jelly or foam with condoms or diaphragm], contraceptive patch, or surgical sterilization) before entry and throughout the study
- Females with reproductive potential who do not have a negative urine beta-human chorionic gonadotropin pregnancy test at screening
- Major surgery without full recovery or major surgery within 3 weeks of ON 01910.Na treatment start
- Uncontrolled hypertension (defined as systolic pressure 160 mmHg and/or diastolic pressure 110 mmHg)
- New onset seizures (within 3 months prior to first dose of ON 01910.Na) or poorly controlled seizures
- Any other concurrent investigational agent or chemotherapy, radiotherapy, or immunotherapy
- Prior treatment with low-dose cytarabine during past 2 years Investigational therapy within 4 weeks of starting ON 01910.Na
- Psychiatric illness or social situation that limits the patient's ability to tolerate and/or comply with study requirements

Alter >= 18 Jahre

Status Rekrutierung beendet

Beginn der Rekrutierung 01.11.2010

Fallzahl 270

Ansprechpartner

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Sponsoren Onconova Therapeutics, Inc. (Hauptsponsor)

Förderer Onconova Therapeutics, Inc.

Registrierung in anderen Studienregistern	ClinicalTrials.govNCT01241500 European Clinical Trials Database - EUDRACT2010-019755-21