Effect of Moderate Renal Impairment and Race/Ethnicity on Treosulfan Pharmacokinetics

Status: RECRUITING

Eligibility Criteria

Age: 18 years to 80 years old

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

1. Participants with AML or MDS who qualify for treosulfan-based conditioning treatment, indicated for alloHSCT. 2. Have available matched-related, matched-unrelated, haploidentical, or a mismatched unrelated donor. Match is defined as at least 9/10 allele matches in human leucocyte antigen (HLA)-A, -B, -C, -DRB1 and DQB1 or 7/8 allele matches in (HLA)-A, -B, -C and -DRB1. Haploidentical is defined as any family member with 2, 3 or 4 (out of 8) HLA-loci mismatch; at the same time, the donor and recipient must be HLA identical for at least one antigen at the following genetic loci: (HLA)-A, -B, -C, and -DRB1. High resolution deoxyribonucleic acid (DNA) typing must be used. 3. Are adults of either sex, age 18-80 years (inclusive). 4. Have a Karnofsky Index of greater than or equal to (\>=) 60 percent (%). 5. Have a creatinine clearance (CLcre) \>=30 milliliters per minute (mL/min) (Cockcroft Gault: normal renal function: CLcre \>=90 mL/min, mild renal impairment: CLcre 60-89 mL/min, moderate renal impairment: CLcre 30-59 mL/min). 6. Are willing to consent to using a highly effective method of birth control, such as condoms, implants, injectables, combined oral contraceptives, intrauterine devices, sexual abstinence or vasectomised partner while on treatment and for at least 6 months thereafter, if females of childbearing potential (defined according to the Clinical Trials Facilitation and Coordination Group guidelines as a fertile woman, following menarche and until becoming postmenopausal unless permanently sterile) and males capable of reproduction. 7. Have a negative pregnancy test, if females of childbearing potential. 8. Have provided a written informed consent.

Exclusion Criteria:

1. Participants considered not eligible for alloHSCT, for instance due to severe concomitant illness, within 3 weeks before the scheduled Baseline Visit: * Have severe renal impairment, example, are on dialysis, have renal transplantation history, or calculated CLcre of less than (\<) 30 mL/min. * Have severe pulmonary impairment, single-breath diffusion capacity of the lung for carbon monoxide (DLCO) (haemoglobin adjusted) or forced expiratory volume (FEV1) of \<50%, or severe dyspnoea at rest or requiring oxygen supplementation. * Have moderate or severe hepatic impairment (Child-Pugh B or C classification, respectively) and with documented medical history of chronic liver disease.. 2. Have a known coronary artery disease, history of myocardial infarction, cardiac dysfunction, including cardiomyopathies, heart failure (New York Heart Association Class II and above), and cardiac arrhythmias (including paroxysmal and permanent atrial fibrillation), interventricular conduction delay and / or bundle branch block (QRS duration \>120 milliseconds \[ms\]). 3. Have Fredericia-corrected QTc (QTcF) interval \>450 ms in men and \>470 ms in women. 4. Have active malignant involvement of the central nervous system. 5. Are human immunodeficiency virus (HIV) positive or have an active non controlled infectious disease under treatment including fungal infection, active viral liver infection, or known severe acute respiratory syndrome coronavirus 2 (SARS CoV 2) viral infection at the time of enrolment. 6. Have previously had more than one alloHSCT. 7. Have pleural effusion or ascites of \>1.0 liters (L). 8. Are pregnant or breast-feeding. 9. Have uncontrolled or severe intercurrent medical condition. 10. Have known hypersensitivity to treosulfan, fludarabine, and / or related ingredients, Fanconi anaemia and other disorders resulting from DNA repair disorders. 11. Are participating in another experimental drug trial (except those for coronavirus disease \[COVID 19\] vaccines) within 4 weeks prior to the Day 7 Baseline Visit. This exception serves to comply with subject's interests as this population is at a high risk of COVID 19 complications, if the disease occurs. COVID 19 vaccination details (including vaccine name, batch and manufacturer, dose, date of administration, and whether the right or left arm was injected) should be captured as a concomitant medication to enable better assessment of the overall effect of COVID 19 vaccination on oncology trial results. 12. Exhibit non cooperative behaviour or non compliance. 13. Have psychiatric diseases or conditions that might compromise the ability to give informed consent.

Conditions & Interventions

Interventions:
DRUG: Treosulfan, DRUG: Fludarabine
Conditions:
Acute Myeloid Leukaemia (AML), Myelodysplastic Syndrome (MDS), Allogeneic Hematopoietic Stem Cell Transplantation (HSCT)
Keywords:
Pharmacokinetic

More Information

Contact(s): Clinical Trial Information - ClinicalTrialInformation@medac.de
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Phase: PHASE1
IRB
Number:
System ID: NCT05534620
