Comparing Combinations of Drugs to Treat Newly Diagnosed Multiple Myeloma (NDMM) When a Stem Cell Transplant is Not a Medically Suitable Treatment

Status: RECRUITING

Eligibility Criteria

Age:

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* Participants must have documented multiple myeloma satisfying standard International Myeloma Working Group (IMWG) diagnostic criteria within 28 days prior to registration * Participants must have measurable disease within 28 days prior to registration as defined by any of the following: * Immunoglobulin (Ig) G myeloma (serum monoclonal paraprotein \[M-protein\] level \>= 0.5 gram/deciliter \[g/dL\] or urine M-protein level \>= 200 milligram\[mg\]/24 hours\[hrs\]); OR * IgA, IgM, IgD, or IgE multiple myeloma (serum M-protein level \>= 0.2 g/dL or urine M-protein level \>= 200 mg/24 hrs); OR * Light chain multiple myeloma (serum immunoglobulin free light chain \>= 10 mg/dL and abnormal serum immunoglobulin kappa lambda free light chain ratio) * All disease must be assessed and documented on the baseline/pre-registration tumor assessment form * Participants must have a calculated myeloma frailty index (Myeloma Frailty Score Calculator; http://www.myelomafrailtyscorecalculator.net/) categorized as frail or intermediate fit (regardless of age) within 28 days prior to registration * For Participants Meeting "Frail" Status: * Participants with any degree of kidney dysfunction are allowed; however, participants on dialysis are not eligible * For Participants Meeting "Frail" Status: * Hemoglobin \>= 7 g/dL (must be performed within 28 days prior to registration) * Note: growth factor and transfusion utilization are allowed if cytopenias are considered secondary to bone marrow involvement from MM) * For Participants Meeting "Frail" Status: * Platelets \>= 50 x 10\^9/L (must be performed within 28 days prior to registration) * Note: growth factor and transfusion utilization are allowed if cytopenias are considered secondary to bone marrow involvement from MM) * For Participants Meeting "Frail" Status: * Absolute neutrophil count (ANC) \>= 0.75 x10\^9/L (must be performed within 28 days prior to registration) * Note: growth factor and transfusion utilization are allowed if cytopenias are considered secondary to bone marrow involvement from MM) * For Participants Meeting "Intermediate Fit" Status, one or more of the following criteria must be present: * Kidney dysfunction showing calculated creatinine clearance (CrCl) \<30 ml/min. * Actual lab serum creatinine value with a minimum of 0.7 mg/dL. * Participants must have bone marrow function assessed and meet the below criteria ranges: * Hemoglobin between 7-8 g/dL, OR * Platelets between 50-75 x10\^9/L, OR * ANC between 0.75-1 x10\^9/L * Note: growth factor and transfusion utilization are allowed as long as cytopenias are considered secondary to bone marrow involvement from MM) * Revised International Staging System (R-ISS) stage III disease * Note: All labs must be performed within 28 days prior to registration * Participants must have a complete medical history and physical exam within 28 days prior to registration * Participants must have whole body imaging within 60 days prior to registration. The recommended method of imaging is a positron emission tomography/computed tomography (PET/CT); a low-dose whole body CT scan or whole-body magnetic resonance imaging (MRI) or skeletal survey should be done only if a PET/CT scan cannot be done or is non-feasible. This must be documented in the comments section of the Onstudy form. * Total bilirubin =\< 2 times institutional upper limit of normal (ULN) unless history of Gilbert's disease. Participants with history of Gilbert's disease must have total bilirubin =\< 5 x institutional ULN (within 28 days prior to registration) * Aspartate aminotransferase (AST)/alanine aminotransferase (ALT) =\< 3 × institutional ULN (within 28 days prior to registration) * Participants must have adequate cardiac function, as assessed by the treating physician within 14 days prior to registration. Participants with known history or current symptoms of cardiac disease, or history of treatment with cardiotoxic agents, must have a clinical risk assessment of cardiac function using the New York Heart Association Functional Classification and must not be assessed as class 3 or 4 * Participants with known diabetes must show evidence of controlled disease within 14 days prior to registration. Uncontrolled diabetes is defined as: A glycosylated hemoglobin (Hg)A1C \> 7 * Participants with known human immunodeficiency virus (HIV)-infection must be receiving anti-retroviral therapy and have an undetectable viral load test on the most recent test result obtained, within 6 months prior to registration * All participants with evidence of chronic hepatitis B virus (HBV) infection must have undetectable HBV viral load on suppressive therapy within 28 days prior to registration * Participants with a history of hepatitis C virus (HCV) infection must have been treated and cured. For participants with HCV infection who are currently on treatment, participant must have an undetectable HCV viral load within 28 days prior to registration * Participants must have an Eastern Cooperative Oncology Group (ECOG)/Zubrod performance status score of 0-2 (Note: Participants with ECOG/Zubrod performance score \[PS\] 3, especially where the deterioration of PS is considered secondary to the MM diagnosis, will be allowed) * Participants must be offered the opportunity to participate in specimen banking. With participant consent, specimens must be collected and submitted via the Southwest Oncology Group (SWOG) specimen tracking system * Participants who are able to complete the patient-reported outcomes measures in English or Spanish must agree to participate in the PRO portion of the study * Participants must be informed of the investigational nature of this study and must sign and give informed consent in accordance with institutional and federal guidelines. For participants with impaired decision-making capabilities, legally authorized representatives may sign and give informed consent on behalf of study participants in accordance with applicable federal, local, and Central Institutional Review Board (CIRB) regulations

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Exclusion Criteria:

* Participants must not have received any prior systemic therapy for multiple myeloma with the exception of any one or more of the following: * An emergency use of a short course of corticosteroids (equivalent of dexamethasone 160 mg) any time before registration, or * Up to one complete cycle of a non-daratumumab and hyaluronidase-fihj containing anti-myeloma regimen (1 cycle = 21 or 28 days depending on the regimen being used), or * Localized palliative radiation therapy for multiple myeloma, as long as the radiation therapy is completed at least 3 days prior to starting the systemic treatment as per the study protocol. * Participants must not have evidence of grade 4 peripheral neuropathy prior to study registration * Participants must not have uncontrolled blood pressure within 14 days prior to registration. Uncontrolled blood pressure: systolic blood pressure (SBP) \> 140 mmHg or diastolic blood pressure (DBP) \> 90 mmHg. Participants are permitted to be receiving multiple anti-hypertensive medications (unless otherwise indicated in the study). All blood pressure measurements within the 14 days prior to registration must be SBP =\< 140 and DBP =\< 90. A participant with a single blood pressure elevation who upon rechecking has a normal blood pressure will remain eligible at the discretion of the registering investigator. * Participants must not have a prior or concurrent malignancy whose natural history or treatment (in the opinion of the treating physician) has the potential to interfere with the safety or efficacy assessment of the investigational regimen. * Participants must not be pregnant or nursing. Individuals who are of reproductive potential must have agreed to use an effective contraceptive method with details provided as a part of the consent process. A person who has had menses at any time in the preceding 24 consecutive months or who has semen likely to contain sperm is considered to be of "reproductive potential." In addition to routine contraceptive methods, "effective contraception" also includes refraining from sexual activity that might result in pregnancy and surgery intended to prevent pregnancy (or with a side-effect of pregnancy prevention) including hysterectomy, bilateral oophorectomy, bilateral tubal ligation/occlusion, and vasectomy with testing showing no sperm in the semen.

Conditions & Interventions

Interventions:

DRUG: Bortezomib, DRUG: Daratumumab and Hyaluronidase-fihj, DRUG: Dexamethasone, DRUG: Lenalidomide, OTHER: Quality-of-Life Assessment, OTHER: Questionnaire Administration

Conditions:

Plasma Cell Myeloma

Plasma Cell Myeloma

More Information

Contact(s): Sharon Palmer - spalmer@swog.org
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IRB
Number:
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