

AOST2032; A Feasibility and Randomized Phase 2/3 Study of the VEGFR2/MET Inhibitor Cabozantinib in Combination with Cytotoxic Chemotherapy for Newly Diagnosed Osteosarcoma

Status: Recruiting

Eligibility Criteria

Sex: Male or Female

Age Group: 18 years and over

This study is NOT accepting healthy volunteers

Inclusion Criteria:

1. less than 40 years old 2. new diagnosis of osteosarcoma of any site

Exclusion Criteria:

1. previous treatment for osteosarcoma 2. brain metastasis 3. history of high blood pressure (140/90) that has required medication 4. women who are pregnant or breast feeding

Conditions & Interventions

Interventions:

Procedure: Bone Scan, Drug: Cabozantinib S-malate, Drug: Cisplatin, Procedure: Computed Tomography, Drug: Doxorubicin Hydrochloride, Procedure: Magnetic Resonance Imaging, Drug: Methotrexate, Procedure: Surgical Procedure, Procedure: X-Ray Imaging

Conditions:

Cancer

Keywords:

Osteosarcoma

More Information

Description: This phase II/III trial tests the safety, side effects, and best dose of the drug cabozantinib in combination with standard chemotherapy, and to compare the effect of adding cabozantinib to standard chemotherapy to standard chemotherapy alone in treating patients with newly diagnosed osteosarcoma. Cabozantinib is in a class of medications called kinase inhibitors. It works by blocking the action of an abnormal protein that signals tumor cells to multiply. This helps slow or stop the spread of tumor cells. The drugs used in standard chemotherapy for this trial are methotrexate, doxorubicin, and cisplatin. Methotrexate stops cells from making DNA and may kill tumor cells. It is a type of antimetabolite. Doxorubicin is in a class of medications called anthracyclines. It works by slowing or stopping the growth of tumor cells in the body. Cisplatin is in a class of medications known as platinum-containing compounds. It works by killing, stopping or slowing the growth of tumor cells. Adding cabozantinib to standard chemotherapy may work better in treating newly diagnosed osteosarcoma.

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Phase: PHASE2

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