

SarcomaCancer

A study to look at the effectiveness of chemotherapy plus bevacizumab compared with chemotherapy alone in children and adolescents with metastatic soft tissue sarcoma (STS) (BERNIE)

A Study of Avastin (Bevacizumab) in Combination With Standard Chemotherapy in Children and Adolescents With Sarcoma.

Trial Status
Completed

Trial Runs In
13 Countries

Trial Identifier
NCT00643565 2007-005017-19
BO20924

The information is taken directly from public registry websites such as ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., and has not been edited.

Official Title:

An Open-label, Multi-center, Randomized Study of the Safety and Effect on Event-free Survival of Bevacizumab in Combination With Standard Chemotherapy in Childhood and Adolescent Patients With Metastatic Rhabdomyosarcoma and Non-rhabdomyosarcoma Soft Tissue Sarcoma

Trial Summary:

This open-label two-arm study will assess the safety and efficacy of a combination of bevacizumab + standard chemotherapy with standard chemotherapy alone as active comparator in childhood and adolescent patients with metastatic rhabdomyosarcoma or non-rhabdomyosarcoma soft tissue sarcoma. Patients will be randomized to receive bevacizumab + standard chemotherapy or standard chemotherapy alone. Treatment will consist of 9 x 3-week cycles of induction treatment (standard chemotherapy with or without bevacizumab 7.5 mg/kg iv on day 1 of each cycle) followed by 12 x 4-week cycles of maintenance treatment (standard chemotherapy with or without bevacizumab 5 mg/kg iv on days 1 and 15 of each cycle). The anticipated time on study treatment is 1-2 years.

Hoffmann-La Roche
Sponsor

Phase 2
Phase

NCT00643565 2007-005017-19 BO20924
Trial Identifiers

Eligibility Criteria:

Gender

Age

Healthy Volunteers

ForPatients

by Roche

All

#6 Months & # 18 Years

No

Inclusion Criteria:

- childhood and adolescent patients aged ≥ 6 months to 18 years of age
- metastatic rhabdomyosarcoma or non-rhabdomyosarcoma soft tissue sarcoma
- adequate bone marrow function
- adequate renal and liver function
- adequate blood clotting

Exclusion Criteria:

- previous malignant tumors
- tumor invading major blood vessels
- prior systemic anti-tumor treatment