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Metronomic and Targeted Anti-angiogenesis Therapy for Children With Recurrent/Progressive Medulloblastoma (MEMMAT)

This study is currently recruiting participants.

See Contacts and Locations

Verified May 2017 by Andreas Peyrl, Medical University of Vienna
Sponsor:
Medical University of Vienna
Information provided by (Responsible Party):
Andreas Peyrl, Medical University of Vienna
ClinicalTrials.gov Identifier:
NCT01356290
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History of Changes

- Full Text View
- Tabular View
- No Study Results Posted
- Disclaimer
- How to Read a Study Record

Purpose

Patients with relapsed medulloblastoma have a very poor prognosis whether treated with conventional chemotherapy, high-dose chemotherapy with stem cell rescue, irradiation or combinations of these modalities. Antiangiogenetic therapy has emerged as new treatment option in solid malignancies. The frequent, metronomic schedule targets both proliferating tumor cells and endothelial cells, and minimizes toxicity. In this study the investigators will evaluate the use of biweekly intravenous bevacizumab in combination with five oral drugs (thalidomide, celecoxib, fenofibrate, and alternating cycles of daily low-dose oral etoposide and cyclophosphamide), augmented with alternating courses of intrathecal etoposide and liposomal cytarabine. The aim of the study is to extend therapy options for children with recurrent or progressive medulloblastoma, for whom no known curative therapy exists, by prolonging survival while maintaining good quality of life. The primary objective of the MEMMAT trial is to evaluate the activity of this multidrug antiangiogenic approach in these heavily pretreated children and young adults. Additionally, progression-free survival (PFS), overall

survival (OS), as well as feasibility and toxicity will be examined.

Condition	Intervention	Phase
Medulloblastoma	Drug: Bevacizumab Drug: Thalidomide Drug: Celecoxib Drug: Fenofibric acid Drug: Etoposide Drug: Cyclophosphamide Drug: Etoposide phosphate Drug: Liposomal cytarabine	Phase 2

Study Type: Interventional
Study Design: Intervention Model: Single Group Assignment
Masking: None (Open Label)
Primary Purpose: Treatment

Official Title: A Phase II Study of Metronomic and Targeted Anti-angiogenesis Therapy for Children With Recurrent/Progressive Medulloblastoma

Resource links provided by NLM:

Genetic and Rare Diseases Information Center resources: Medulloblastoma Glioma Neuroepithelioma

U.S. FDA Resources

Further study details as provided by Andreas Peyrl, Medical University of Vienna:

Primary Outcome Measures:

- Efficacy [Time Frame: 8 years]

  Response rate (Complete remission, partial response, stable disease =[CR+PR+SD]/n) 6 months after start of antiangiogenic treatment

Secondary Outcome Measures:

- Overall survival rate [Time Frame: 8 years]

  The percentage of patients in the study who are alive for a certain period of time (6, 12, 24, and 36 months) after start of treatment with an antiangiogenic multidrug-regime

- Progression free survival rate [Time Frame: 8 years]

  The percentage of patients in the study who are alive with a non-progressive disease for a certain period of time (6, 12, 24, and 36 months) after start of treatment with an antiangiogenic multidrug-regime.

- Toxicity [Time Frame: 8 years]

  To evaluate and document toxicities from chronic administration of these drugs at the doses prescribed in this protocol in patients with recurrent or progressive medulloblastoma. These will be descriptive in nature.

- Feasibility [Time Frame: 6 years]

  To evaluate the feasibility of achieving the prescribed drug doses given the reduced bone marrow tolerance after multiple relapses.

- Quality of life [Time Frame: 8 years]

  Quality of Life (QoL) will be evaluated by a generic quality of life instrument for children (the KINDL®-questionnaire).

- Prognostic factors [Time Frame: 8 years]

  To evaluate the influence of tumor biology(histologic subgroups, metastatic stage, age at first diagnosis [<3 years, >3 years])

To evaluate the influence of tumor biology (histologic subgroups, metastatic stage, age at first diagnosis [<3 years, >3 years]), age at start of antiangiogenic therapy, sex, duration of remission prior to antiangiogenic therapy, number of recurrences.

- Angiogenic factors [Time Frame: 8 years]

  To evaluate serum markers for in-vitro correlative studies of tumor response.

Estimated Enrollment:	40
Study Start Date:	April 2014
Estimated Study Completion Date:	April 2022
Estimated Primary Completion Date:	April 2019 (Final data collection date for primary outcome measure)

Intervention Details:

Drug: Bevacizumab

10mg/kg, intravenous (iv), biweekly, 1 year

Other Name: Avastin

Drug: Thalidomide

3mg/kg, oral, daily, 1 year

Drug: Celecoxib

50-400mg, oral bid, daily, 1 year

Drug: Fenofibric acid

90mg/m2, oral, daily, 1 year

Drug: Etoposide

35-50 mg/m2, oral, alternating 21-day cycles of daily oral etoposide and cyclophosphamide, 1 year

Drug: Cyclophosphamide

2.5mg/kg, oral, alternating 21-day cycles of daily oral etoposide and cyclophosphamide, 1 year

Drug: Etoposide phosphate

0.5mg, intrathecal, day 1-5, every four weeks, alternating with intrathecal liposomal cytarabine, 1 year

Drug: Liposomal cytarabine

25-35mg, intrathecal, every four weeks, alternating with intrathecal etoposide phosphate, 1 year

Eligibility

Ages Eligible for Study:	up to 19 Years (Child, Adult)
Sexes Eligible for Study:	All
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Relapsed or progressive medulloblastoma (at least one site of untreated recurrent disease)
- Histological confirmation of medulloblastoma at diagnosis or relapse
- Female or male, aged from 0 to <20 years (at time of original diagnosis)
- Participants must have normal organ and bone marrow function (ALT <5x institutional upper limit of normal, creatinine <1.5x institutional upper limit of normal for age, WBC >1000/mm3, platelets > 20,000/mm3. Patients with values less than WBC 2000/mm3 or platelets 50,000/mm3 will require initiation of treatment with etoposide and cyclophosphamide at a lower starting dose as defined within the protocol.
- Karnofsky performance status ≥50. For infants and children less than 12 years of age, the Lansky play scale ≥50% will be used
- Written informed consent of patients and / or parents

Exclusion Criteria:

- Active infection
- VP-shunt dependency
- Pregnancy or breast feeding
- Conventional chemotherapy, antiangiogenic treatment or complete irradiation of all disease for current relapse (surgery may be performed before antiangiogenic treatment; patients with sites of disease not irradiated are still eligible for the protocol)
- Known hypersensitivity to any of the drugs in the protocol
- Active peptic ulcer
- Any significant cardiovascular disease not controled by standard therapy e.g. systemic hypertension
- Anticipation of the need for major elective surgery during the course of the study treatment
- Any disease or condition that contraindicates the use of the study medication/treatment or places the patient at an

unacceptable risk of experiencing treatment-related complications

- Non-healing surgical wound
- A bone fracture that has not satisfactorily healed

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT01356290

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Keywords provided by Andreas Peyrl, Medical University of Vienna:

Medulloblastoma	antiangiogenic
Relapse	metronomic
Children	intrathecal

Additional relevant MeSH terms:

Medulloblastoma	Cytarabine
Glioma	Celecoxib
Neoplasms, Neuroepithelial	Fenofibric acid
Neuroectodermal Tumors	Angiogenesis Inhibitors
Neoplasms, Germ Cell and Embryonal	Angiogenesis Modulating Agents
Neoplasms by Histologic Type	Growth Substances
Neoplasms	Physiological Effects of Drugs
Neuroectodermal Tumors, Primitive	Growth Inhibitors
Neoplasms, Glandular and Epithelial	Antineoplastic Agents
Neoplasms, Nerve Tissue	Immunosuppressive Agents
Bevacizumab	Immunologic Factors
Thalidomide	Antirheumatic Agents
Etoposide phosphate	Antineoplastic Agents, Alkylating
Cyclophosphamide	Alkylating Agents
Etoposide	Molecular Mechanisms of Pharmacological Action

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