PLEASE NOTE: *This study has been imported from ClinicalTrials.gov without additional data checks.*

Trial Description

Title

Cooperative Multicenter Study for Children and Adolescents With Low Grade Glioma

Trial Acronym

SIOP-LGG-2004

URL of the trial

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Brief Summary in Lay Language

RATIONALE: Radiation therapy uses high-energy x-rays to kill tumor cells. Drugs used in chemotherapy, work in different ways to stop the growth of tumor cells, either by killing the cells or by stopping them from dividing.

PURPOSE: This clinical trial is studying giving radiation therapy or combination chemotherapy to see how well it works in treating patients with clinically or radiologically progressive low-grade gliomas.

Brief Summary in Scientific Language

OBJECTIVES:

- Provide a comprehensive treatment strategy for children and adolescents with low-grade glioma of all tumour locations and histologies.

- Provide standardized treatment indication and treatment recommendations for non-surgical therapy in children and adolescents with low grade glioma without and with associated neurofibrosis-type 1 (NF1) at diagnosis or after observation.

- Determine overall, event-free, and progression-free survival.

- Radiotherapy arm: a. Determine progression free survival in older children without NF1

treated with radiotherapy using modern techniques for planning and treatment. b.
Determine the reduction of the rate and intensity of possible late effects of therapy
to the organs at risk by optimized planning and treatment.

- Chemotherapy arm: a. Determine progression free survival for younger children without
NF1 treated with chemotherapy and randomized to either the 2-drug or the 3-drug
induction regimen. b. Determine the distribution of response at week 24 (after
induction) for younger children without NF1 treated with chemotherapy and randomized to
either the 2-drug or the 3-drug induction regimen. c. Determine progression free
survival for children with NF1treated with chemotherapy.

- Determine the influence of clinical and histological findings on overall survival,
progression-free and event-free survival in these patients.

- Determine prospectively the late effects of tumor and therapy in these patients.

OUTLINE: This is a partially randomized, open-label, multicenter study.

Children with completely resected tumors, incompletely resected tumors, or those with
clinically/neuroradiologically diagnosed tumors, who do not have severe symptoms at
diagnosis, are only observed during follow-up.

Children with unresectable/incompletely-resectable tumors, or those with relapsed disease
and those observed following incomplete initial resection or neuroradiologic diagnosis and
clinical and/or neuro-radiologic progression receive non-surgical therapy. This non-surgical
therapy is either chemotherapy (for children younger than 8 years and those with
neurofibrosis-type 1 [NF1]) or radiotherapy (for children older than 8 years).

- Chemotherapy: Within the chemotherapy arm, patients without NF1 are randomized to
receive 1 of 2 induction chemotherapy regimens. Patients with NF1 receive the two-drug
induction therapy as in arm I.

- Arm I (two-drug induction therapy [vincristine-carboplatin]): Patients receive
induction therapy comprising vincristine IV on day 1 of weeks 1-10 and weeks 13,
17, and 21 and carboplatin IV over 1 hour on day 1 of weeks 1, 4, 7, 10, 13, 17,

and 21.

- Arm II (three-drug induction therapy [vincristine-carboplatin-etoposide]):
Patients receive vincristine and carboplatin as in two-drug induction therapy.
Patients also receive etoposide IV over 1 hour on days 1-3 of weeks 1, 4, 7, and 10.

Beginning in week 25, all patients in the chemotherapy arm receive consolidation therapy comprising vincristine IV on days 1, 8, and 15 and carboplatin IV over 1 hour on day 1.
Treatment repeats every 6 weeks for 9 courses. Patients experiencing disease progression or an allergic reaction to carboplatin receive vincristine IV on days 1, 8, and 15 and either cyclophosphamide IV over 1 hour on day 1 or cisplatin IV over 3 hours on days 1 and 2.
Treatment repeats every 6 weeks for 5 courses. All patients in the chemotherapy arm receive a total of 18 months of treatment.

- Radiotherapy: Conventional external beam fractionated radiotherapy is given at standard doses for children receiving radiotherapy. Brachytherapy can be given, if tumors are suitable for this type of treatment.

After completion of study treatment, patients are followed periodically for 10 years.

PROJECTED ACCRUAL: A total of 520 patients will be accrued for the randomized arm of this study.

Organizational Data

- DRKS-ID: **DRKS00003771**
- Date of Registration in DRKS: **2012/05/04**
- Date of Registration in Partner Registry or other Primary Registry: **2006/01/12**
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **[---]***
- (leading) Ethics Committee Nr.: **[---]***

Secondary IDs

- EudraCT-No.
(for studies acc. to Drug Law): **2005-005377-29**
- Primary Registry-ID: **NCT00276640 (ClinicalTrials.gov)**

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- Sponsor-ID: **CDR0000454506 (Societe Internationale d'Oncologie Pediatrique)**
- Other Secondary-ID: **2005-005377-29**

Health condition or Problem studied

- Free text: **Brain and Central Nervous System Tumors**

Interventions/Observational Groups

- Arm 1: **Drug: vincristine, carboplatin**
- Arm 2: **Drug: vincristine, carboplatin, etoposide**
- Arm 3: **Radiation: radiation therapy**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Non-randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Active control (effective treament of control group), Control group receives no treatment**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

- Progression-free survival; time frame: week 24, and at 1, 3, and 5 years
- Event-free survival; time frame: week 24 and at 1, 3, and 5 years
- Overall survival; time frame: week 24 and at 1, 3, and 5 years

Secondary Outcome

- Response week 24; time frame: week 24; radiological response to therapy (chemotherapy or radiation therapy)

Countries of recruitment

- AT **Austria**
- BE **Belgium**
- HR **Croatia**
- DK **Denmark**
- FR **France**
- DE **Germany**
- IT **Italy**
- NO **Norway**
- PL **Poland**
- PT **Portugal**
- CH **Switzerland**
- UK **United Kingdom**

Locations of Recruitment

- **Klinikum Augsburg, Augsburg**

Recruitment

- Planned/Actual: **[---]***
- (Anticipated or Actual) Date of First Enrollment: **2004/04/30**
- Target Sample Size: **3000**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **International**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **no minimum age**
- Maximum Age: **18 Years**

Additional Inclusion Criteria

DISEASE CHARACTERISTICS:

- **Histologically confirmed low-grade glioma, of 1 of the following histologic**

subtypes:

- **Pilocytic astrocytoma I° and variants**
- **Subependymal giant cell astrocytoma I°**
- **Dysembryoplastic neuroepithelial tumor I°**
- **Desmoplastic infantile ganglioglioma I°**
- **Ganglioglioma I° and II°**
- **Pleomorphic xanthoastrocytoma II°**
- **Oligodendroglioma II°**
- **Oligoastrocytoma II°**
- **Astrocytoma II°**
  - **Fibrillary astrocytoma II°**
  - **Protoplasmatic astrocytoma II°**
  - **Gemistocytic astrocytoma II°**

- **Children with chiasmatic-hypothalamic tumors may be eligible without histological diagnosis, if neuroradiologic findings meet unequivocal criteria for the presence of a low-grade glioma**

- **Primary tumor localization: intracranial and/or spinal cord**

  - **No diffuse intrinsic tumors of the pons, even if histologically an astrocytoma I° or II° is diagnosed**

    - **Exception: pontine glioma II° in neurofibromatosis type 1 (NF1) disease allowed**

- **Children presenting with disseminated low-grade glioma will be eligible for the study**

- **All eligible patients without NF1 disease receiving chemotherapy as their first nonsurgical therapy are eligible for randomization**

- **Children are eligible for the trial regardless of the presence of associated genetic disease: NF1 disease will be the prominent one, all children with NF1 disease are entered into the study arm III in case of an indication for nonsurgical therapy**

- Patients presenting with rare intracranial neoplasms of low-grade malignancy, but nonglial origin, may be followed according to the low-grade glioma strategy, but they are not subject of this therapy trial.

- Data from these patients may be registered to learn about those therapeutic interventions which may prove useful to these patients and to develop separate strategies in the future

- Patients with choroid plexus papilloma should be entered into the SIOP-CPT study (Prof. Dr. J. Wolff, M.D. Anderson Cancer Center, Houston, Texas)

PATIENT CHARACTERISTICS:

- No preexisting impairments of health status, making the conduct of the study impossible or ethically unwise

- No evidence of pregnancy or lactation period

- Pregnancy has to be prevented in fertile adolescent girls during chemotherapy by reliable contraception methods (e.g., hormonal contraception)

PRIOR CONCURRENT THERAPY:

- The tumor should not be pretreated with chemotherapy or radiotherapy

- Children treated with chemotherapy or radiotherapy prior to entering the study will be evaluated separately

- Previous treatment with steroids is not considered a chemotherapeutic treatment

- Surgery of any type and extent allowed

- Prior surgical resection of the tumor allowed

- Participation in another clinical study concurrently with this study (e.g., endocrinologic study) allowed provided it is not interfering with the present treatment strategy

- No other concurrent chemotherapy

- Concurrent medication for associated or other conditions (e.g., hormone replacement, anticonvulsants) that does not containing cytostatic drugs allowed

Exclusion criteria

[---]*

Addresses

- **Primary Sponsor**

  Societe Internationale d'Oncologie Pediatrique

  Telephone: **[---]***
  Fax: **[---]***
  E-mail: **[---]***
  URL: **[---]***

- **Contact for Scientific Queries**

  Klinikum Augsburg
  Astrid Gnekow

  Telephone: **[---]***
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  URL: **[---]***

- **Contact for Public Queries**

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  E-mail: **[---]***
  URL: **[---]***

Sources of Monetary or Material Support

- **[---]***

  Bitte wenden Sie sich an den Sponsor / Please refer to primary sponsor

  Telephone: **[---]***
  Fax: **[---]***

[---]*

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Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

Status

- Recruitment Status: **Recruiting ongoing**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

- Further trial documents **Clinical trial summary from the National Cancer Institute's PDQ® database**

The parameters in ClinicalTrials.gov and DRKS are not identical. Therefore the data import from ClinicalTrials.gov required adjustments. For full details please see the DRKS FAQs.
- Translation on version: 8
- Last processed date by ClinicalTrials.gov: 2013/10/30

** This entry means the parameter is not applicable or has not been set.*

**** This entry means that data is not displayed due to insufficient data privacy clearing.*