A study for all children and adolescents with a low grade glioma.

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The goal of this study is: 1. To offer a uniform, standardized concept for the treatment of children and adolescents affected by low grade glioma; 2. To improve progression free survival following non-surgical therapy for children without NFI with...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20306

Bron
NTR

Verkorte titel
SIOP-LGG-2004

Aandoening

low grade glioma, laaggradig glioom

Ondersteuning

Primaire sponsor: International: SIOP
De voorzitter van de Trial Management Committee:
Dr. Astrid K. Gnekow
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National: Dutch Childhood Oncology Group (DCOG)
Overige ondersteuning: Dutch Childhood Oncology Group (DCOG)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Progression Free Survival.

Toelichting onderzoek

Achtergrond van het onderzoek

The study SIOP-LGG 2004 offers a common therapy strategy for all children and adolescents with a histologically (WHO criteria) or radiologically confirmed low grade glioma. Following complete resection patients will only be observed, as will be patients without symptoms or progression after incomplete resection or clinical diagnosis. Non-surgical therapy will be instituted at the presence of defined indications following incomplete resection, non-resectable relapse or progression of an unresectable tumor.
Older children (³ 8 years) receive primary radiotherapy. Modern planning and treatment techniques shall reduce long term side effects upon surrounding tissues and organs at risk. At the presence of specific conditions these children may receive chemotherapy as well. The indication for interstitial radiotherapy is not age restricted. Younger children (< 8 years) receive primary chemotherapy. Children affected by Neurofibromatosis NF I shall be treated with chemotherapy at all ages. The duration of chemotherapy is 18 months. Children without NF I (stratified for age and tumor localization) will be randomized to receive standard induction with Vincristin and Carboplatin or intensified induction with Vincristin, Carboplatin and Etoposide, to test, if there is a difference in progression free survival. Additionally the distribution of tumor response at week 24 shall be investigated. Consolidation consists of ten 6-week cycles of Vincristin/Carboplatin therapy. For all children overall survival, progression free and event free survival will be calculated. The influence of clinical and histologic findings upon these parameters will be investigated. The extent of late effects of primary tumor and therapy shall be documented prospectively.

Doel van het onderzoek

The goal of this study is:

1. To offer a uniform, standardized concept for the treatment of children and adolescents affected by low grade glioma;

2. To improve progression free survival following non-surgical therapy for children without NFI with low grade glioma (incl. randomisation standard vs intensified induction therapy);

3. To investigate standardized treatment recommendations for non-surgical therapy for the study group of children with NFI and low grade glioma;

4. To reduce the rate and intensity of possible late effects of therapy.

Onderzoeksopzet

1. PFSr: Progression free survival measured from the time of randomization: Time from randomization up to an event:
Definition of event:

A. Death (for all reasons);

B. Progression of a residual tumor;

C. Relapse following previous complete remission;

D. Appearance of new or progression of existing metastasis.

2. Radiological response measured at week 24: Complete, partial, objective responses and stable disease will be considered positive responses in this protocol;

3. PFSd: Progression free survival measured from the time of diagnosis: Time from diagnosis up to an event (definitions of event see 1.);

4. EFSr: Event free survival measured from the time of randomization: Time from randomization up to an event.
Definition of event:

A. Death (for all reasons);

B. Progression of a residual tumor;

C. Relapse following previous complete remission;

D. Appearance of new or progression of existing metastasis;

E. Severe adverse event / toxicity (not counting Carboplatin hypersensitivity and toxicity of regular protocol application);

F. Appearance of secondary malignant neoplasm.

5. EFSd: Event free survival measured from the time of diagnosis: Time from diagnosis up to an event. (definition of event: see 4.);

6. OSr: Overall survival measured from the time of randomization: Interval starting with the day of randomization and ending with the death of the patient independently of its cause;

7. OSd: Overall survival measured from the time of diagnosis: Interval starting with

the day of diagnosis and ending with the death of the patient independently of its cause.

Onderzoeksproduct en/of interventie

Following complete resection patients will only be observed, as will be patients without symptoms or progression after incomplete resection or clinical diagnosis. Non-surgical therapy will be instituted at the presence of defined indications following incomplete resection, non-resectable relapse or progression of an unresectable tumor.

Older children (>= 8 years) receive primary radiotherapy. Modern planning and treatment techniques shall reduce long term side effects upon surrounding tissues and organs at risk. At the presence of specific conditions these children may receive chemotherapy as well. The indication for interstitial radiotherapy is not age restricted. Younger children (< 8 years) receive primary chemotherapy. Children affected by Neurofibromatosis NF I shall be treated with chemotherapy at all ages. The duration of chemotherapy is 18 months. Children without NF I (stratified for age and tumor localization) will be randomized to receive standard induction with Vincristin and Carboplatin or intensified induction with Vincristin, Carboplatin and Etoposide, to test, if there is a difference in progression free survival. Additionally the distribution of tumor response at week 24 shall be investigated. Consolidation consists of ten 6-week cycles of Vincristin/Carboplatin therapy.

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Age: Children and adolescents up to age 16 years;

2. Histology: Glioma of low grade malignancy (ICD O-Codes: 9421/1, 9384/1, 9413/0, 9412/1, 9505/1, 9424/3, 9450/3, 9382/3, 9400/3, 9420/3, 9410/3, 9411/3);

3. Primary tumor localization: Intracranial and spinal cord;

4. Dissemination: Children presenting with disseminated low grade glioma will be eligible for the study;

5. Associated conditions: Children are eligible for the trial regardless of the presence of associated genetic disease;

6. Primary tumor diagnosis: The tumor should not be pretreated with chemotherapy or radiotherapy;

7. Informed consent: The patient and/or his legal guardian (parents) have to have declared their written informed consent to the study.

Within the randomized part of the study all histologies will be randomized, since up to now there are no data to exclude any of the subgroups, e.g. children with oligodendroglioma, from this study.

Specific neuroradiological criteria may allow to diagnose a low grade chiasmatic-hypothalamic tumor without biopsy.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Primary tumor localization: Diffuse intrinsic tumors of the pons, even if histologically an Astrocytoma II° is diagnosed. Exception: pontine glioma II° in NF I patients may be entered into the study;

2. Special diagnosis: Patients presenting with rare intracranial neoplasms of low grade malignancy, but non-glial origin. Their data may be registered however, to learn about those therapeutic interventions which may prove useful to these patients and to develop separate

strategies in the future. Choroid plexus papilloma should be entered on the SIOP-CPT-study;

3. Pretreatment: Children treated with chemo- or radiotherapy prior to entering the study will be evaluated separately. Previous treatment with steroids is not considered a chemotherapeutic treatment;

4. Preexisting impairments of health status, making the conduct of the study impossible or ethically unwise;

5. Evidence of pregnancy or lactation period.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Factorieel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	23-05-2008
Aantal proefpersonen:	100
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	11-04-2012
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3242
NTR-old	NTR3394
Ander register	EudraCT : 2005-005377-29
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A