21.3. Patient Information SIOP - LGG 2004

Declaration of Consent to
21.4.1. Study participation
21.4.2. Data registration
21.4.3. Release of tumor tissue for tumor tissue bank

Accepted national procedures for patient consent are to be used. Therefore these forms have to be designed seperately by each participating national group.

The patient's and/or parent's written consent to participate in the study must be obtained after a full explanation has been given of the treatment options including the conventional and generally accepted methods of treatment and the manner of treatment allocation.
If the patient is a minor, the treatment must be explained to and consent received from his/her guardian. Additionally the child should receive an explanation as to his/her means of understanding and should give consent as well, if he/she is able to do so. Enough time and the opportunity to discuss participation before the decision for and start of treatment have to be given. The right of a patient to refuse to participate without giving reasons must be respected.

Consent for participation in the study and for data management will be obtained separately. If applicable, consent for sending diagnostic material, especially tumor tissue, to reference institutions and tissue banks should be obtained.

21.5.1. Patient Registration - Basic patient data

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(National Coordinating center):

Surname, Prename Pat.-No. Hospital Patient Identity No.
I_____I I_I_I_I_I I__I__I__I__I I__I**I__I__I__I__I__I__I** I__I__I__I__I__I
sex:1=m,2=f date of birth

! Please respect, that written informed consent has to be obtained before this form is forwarded and the information is saved!

Participation in the study:: ❒ (preliminary) observation group ❒ therapy group ❒ no participation

Hereditary disease::
❒ Neurofibromatosis type NFI ❒ no ❒ yes: ❒ familial ❒ sporadic
❒ features present, but international criteria not met
❒ Tuberous Sclerosis ❒ no ❒ yes
❒ other:_____

Circumstances of diagnosis:: ❒ Symptoms of disease
❒ Accidental finding during investigation for another disease
❒ Other:_____

Earliest manifestation of symptoms clearly related to tumor:
before I__I__I weeks / I__I__I months: Tick as appropriate and fill in details:

Symptoms of increased intracranial pressure:	❒ no	❒ yes	_____
Neurologic symptoms:	❒ no	❒ yes	⇒ complete neurology form 21.13.4.
Visual disturbances:	❒ no	❒ yes	⇒ complete ophthalmology form 21.13.6.
Endocrinologic symptoms	❒ no	❒ yes	⇒ complete endocrinology form 21.13.4.
Diencephalic symptoms:	❒ no	❒ yes	_____
Other:	❒ no	❒ yes	_____

Any other symptoms at diagnosis (please detail):_____
_____
_____

Neuro-Radiology at diagnosis (preoperative) - local

Date of diagnosis by imaging: I__I__I . I__I__I . I__I__I__I

❒ **MRI** ❒ with contrast enhancement ❒ without contrast enhancement

❒ **CT** ❒ with contrast enhancement ❒ without contrast enhancement

Tumor size: I__I__I cm x I__I__I cm x I__I__I cm (solid part + cystic part, if present)

Cystic part: ❒ no ❒ yes

Size of the cyst: I__I__I cm x I__I__I cm x I__I__I cm

Ventricular dilatation: ❒ no ❒ yes

Mass effect: ❒ no ❒ yes: ❒ local ❒ midline shift

Histology at first operation (2/3)

❒ **No histology**

❒ **Date of diagnosis by histology:** I__I__I . I__I__I . I__I__I__I__I

Neuropathology (local): _____ **E-No:**_____

Central pathologic review: ❒ **No** ❒ **Yes** **R-No:**_____

Discrepancy of diagnosis: ❒ **No** ❒ **Yes, histology ref. center:**_____

Histopathologic classification and grading according to WHO (Kleihus a. Cavanee, 2000) - <u>local:</u>

1. ❒ Astrocytic tumors
1.1. ❒ Pilocytic astrocytoma
1.1.1. ❒ pilomyxoid variant
1.2. ❒ Astrocytoma nos.
1.2.1. ❒ fibrillary astrocytoma
1.2.2. ❒ protoplasmatic astrocytoma
1.2.3. ❒ gemistocytic astrocytoma
1.3. ❒ Pleomorphic xanthoastrocytoma
1.4. ❒ Subependymal large cell astrocytoma

2. ❒ Oligodendro-glial tumors
2.1. ❒ Oligodendroglioma not otherwise specified

3. ❒ Mixed glioma
3.1. ❒ Oligo-astrocytoma
3.2. ❒ other mixed glioma

4. ❒ Neuronal and mixed glial-neuronal tumors
4.1. ❒ DIGG/DIA - desmoplastic, infantile ganglioglioma/-astrocytoma
4.2. ❒ DNT - dysembryoplastic, neuroepithelial tumor
4.3. ❒ Ganglioglioma
4.4. ❒ atypical myxomatous neuroepithalial tumor

5. ❒ Non-study diagnoses:
❒ Pineocytoma
❒ Choroid plexus papilloma
❒ Neurinoma
❒ acoustic neurinoma (❒ NF II)
❒ Gangliocytoma
❒ other:_____

➡ **Malignancy according to WHO-classification**: ❒ **°I** ❒ **°II** ❒ **°III** ❒ **°IV** (if applicable)

LOCALISATION

(Please underline main localisation and indicate all structures involved)

1. ❒ Cerebral hemisphere
1.1. ❒ frontal lobe
1.2. ❒ parietal lobe
1.3. ❒ temporal lobe
1.4. ❒ occipital lobe

2. ❒ Supratentorial midline
2.1. ❒ Anterior part of optic nerve (including orbital part)
2.2. ❒ Optic chiasm
2.3. ❒ Optic tract
2.4. ❒ Diencephalon
2.4.1. ❒ Hypothalamus
2.4.2. ❒ 3rd ventricle
2.4.3. ❒ Thalamus
2.4.4. ❒ Basal ganglia
2.4.5. ❒ Corpus callosum
2.4.6. ❒ Hypophysis
2.4.7. ❒ Limbic system/Fornix
2.5. ❒ Mesencephalon
2.5.1. ❒ Crus cerebri
2.5.2. ❒ Tegmentum
2.5.3. ❒ Tectum/Lamina quadrigemina
2.5.4. ❒ Pineal region

3. ❒ Cerebellum
3.1. ❒ vermis
3.2. ❒ cerebello-pontine angle
3.3. ❒ hemisphere

4. ❒ Caudal brainstem
4.1. ❒ IVth Ventricle
4.2. ❒ Pons focal
4.3. ❒ Pons intrinsic
4.4. ❒ Medulla oblongata
4.5. ❒ cranio-spinal junction

5. ❒ Spinal canal
5.1. ❒ intraspinal, extradural
5.2. ❒ subdural, extramedullary
5.3. ❒ intramedullary

ad 5.1.-5.3.:
Segments involved:_____

6. ❒ Lateral ventricle
(Giant cell astrocytoma with tuberous sclerosis)

<u>Supplementary to localisation</u>:
_____
_____
_____

Dodge-classification of optic pathway glioma:
❒ **I (Optic nerve only)** ❒ **II (Chiasm ± optic nerve)** ❒ **III (Chiasma + diencephalic extension)**

Side of main tumor localisation: ❒ right ❒ left ❒ on both sides ❒ midline

Primary metastases: ❒ No ❒ Yes, where:_____
(Section 16.1) ❒ M 1 ❒ M 2 ❒ M 3 ❒ M 4

Primary surgical intervention (3/3)

Shunt implantation before/after tumor operation: ❒ no ❒ yes, date: I__I__I . I__I__I . I__I__I__I__I

Type of shunt:_____

Date of surgery: I__I__I . I__I__I . I__I__I__I__I **Hospital, name of surgeon:**_____

_____

Extent of resection:

- ❒ S1 total resection (no visible residual tumor)
- ❒ S2 subtotal resection (residual tumor < 1,5 cm ³ , local invasion)
- ❒ S3 partial resection (residual tumor > 1,5 cm³)
- ❒ S4 biopsy ❒ open ❒ stereotactic ❒ endoscopic

Neuro-Radiology early postoperatively (within 72 hours)

Date: I__I__I . I__I__I . I__I__I__I__I **Technique** ❒ MRI ❒ CT

Contrast enhancement: ❒ no ❒ yes

Size of residual tumor: I__I__I cm x I__I__I cm x I__I__I cm

Finding:

- ❒ R1 no residual tumor
- ❒ R2 contrast enhancement, but small, not measurable
- ❒ R3 residual tumor of a measurable size
- ❒ R4 no change of size as compared to preoperative size (minimal change)

Definit extent of surgery: (SIOP-classification 1995)

		Radiology	Surgery
❒	total resection	R1	S1
❒	subtotal	R1 / R2	S2
❒	partial	R3	S1 / S2 / S3
❒	biopsy	R4	S4

Complete remission achieved? ❒ yes ❒ no

Postoperative management

❒ **Observation (wait and see)**

❒ **Therapy, which:** ❒ **Chemotherapy** ❒ **Radiotherapy** ❒ **Other**

_____

In case of therapy: Please send the appropriate form "Basic therapy information" (21.5.2.) immediately to your national coordinator.

Start of postoperative therapy: I__I__I . I__I__I . I__I__I__I__I

Last date of follow-up: I__I__I . I__I__I . I__I__I__I__I ❒ patient alive ❒ patient dead

Please send for central data management::

❒ pre- and postoperative MRI and CT findings ❒ Histology (local and reference)

❒ surgical report

Remarks:

_____ _____ _____

Stamp **Date** **Signature**

21.5.2. Patient Registration: Basic Therapy Information

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National coordinating center:

Surname, Prename I_____I Pat.-No. I_I_I_I_I Hospital I__I__I__I__I Patient Identity No. I__I **I__I__I__I__I__I__I** I__I__I__I__I__I

date of birth

❒ **Indication for therapy following clinical diagnosis or biopsy** Tick as appropriate:

❒ **Indication for therapy following partial or subtotal resection**

- Diencephalic syndrome	❒ No	❒ Yes
- Focal neurologic deficits secondary to tumor growth	❒ No	❒ Yes
- Seizures secondary to tumor growth	❒ No	❒ Yes
- Increased intracranial pressure secondary to tumor growth	❒ No	❒ Yes
- Definite history of visual deterioration	❒ No	❒ Yes
- Borderline vision ("threat to vision")	❒ No	❒ Yes
- Nystagmus due to visual impairment in infants	❒ No	❒ Yes
- Symptomatic metastases	❒ No	❒ Yes

- Radiological finding: The presence of a postoperative residual tumor is not an indication to therapy by its own.

❒ **Indication to therapy following observation**

- Definite history of visual deterioration	❒ No	❒ Yes
- Manifestation of new neurologic symptoms secondary to tumor growth	❒ No	❒ Yes
- Development of diencephalic syndrome	❒ No	❒ Yes
- Visual deterioration	❒ No	❒ Yes
- Any loss of vision in the second eye, if the other eye is blind	❒ No	❒ Yes
- Increase of tumor size of >25% (increase of the diameter of the optic nerve)	❒ No	❒ Yes
- Involvement of previously uninvolved areas of the brain	❒ No	❒ Yes
- Manifestation of new lesions (including symptomatic or progressive metastases)	❒ No	❒ Yes

Date of last neuroimaging before the start of therapy: I__I__I . I__I__I . I__I__I__I__I (ddmmyyyy)

Tumor size: I__I__I , I__I cm x I__I__I , I__I cm x I__I__I , I__I cm

MRI-images sent for central review? ❒ **Yes** ❒ **No** ❒ **Arranged**

Start of therapy: I__I__I . I__I__I . I__I__I__I__I (ddmmyyyy)

Patient receives: ❒ **Chemotherapy (following randomisation)** ❒ **Radiotherapy**

❒ Induction I + Consolidation

❒ Induction II + Consolidation

❒ conventional radiotherapy

❒ 125-Jodine-Seed-implantation

❒ other: _____

_____

Which hospital provides therapy? _____

_____ stamp

_____ date

_____ signature

21.6.1. Central Randomisation **SIOP LGG 2004**
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(National coordinating center)

Randomisation of Induction-Therapy

Pat.-Identity-Number: I__I I__I__I__I__I__I__I I__I__I__I__I__I

Treatment center / -town: _____

Patient (Surname, Prename): _____

Date of birth: I__I__I . I__I__I . I__I__I__I__I

Neurofibromatosis Type NF I ❒ **No** ❒ Not clear yet

Age of the patient: ❒ < 1 year ❒ < 8 years ❒ ≥ 8 years

Registration form sent? ❒ **Yes** ❒ No ⇒ not eligible

Localisation:

❒ **cerebral hemispheres**
❒ **cerebellum**
❒ **caudal brain stem**
❒ **spinal canal**
❒ **lateral ventricle**
❒ **supratentorial midline**

extension in the case of optic pathway glioma:

❒ Dodge I (optic nerve only) ⇒ not eligible
❒ Dodge II (Chiasma + optic nerve)
❒ Dodge III (Chiasma + extensions)

Date of original diagnosis: ❒ clinical ❒ histological I__I__I . I__I__I . I__I__I__I__I

Date of last resection before chemotherapy: I__I__I . I__I__I . I__I__I__I__I

Previous chemo- or radiotherapie ❒ **No** ❒ **Yes** ⇒ not eligible

Histopathologic diagnosis
Material sent for central review: ❒ No ❒ Yes, date of sending: I__I__I . I__I__I . I__I__I__I__I
❒ Arranged

Histological diagnosis at first operation:_____

Histological diagosis at last operation:_____

WHO-Classification: ❒ °I ❒ °II

MRI (pre- and early postoperatively resp. before start of therapy)
MRI sent for central review: ❒ No ❒ Yes, date of sending: I__I__I . I__I__I . I__I__I__I__I
❒ Arranged

Therapy at: ❒ **diagnosis** ❒ **progression (following observation)**

FAX-No. for response:.....

_____ _____ _____
stamp date signature

21.6.2. Result of Randomisation **SIOP - LGG 2004**
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Treatment center:

FAX-No. of the treatment center:

UPN-Nummer I__I I__I__I__I__I__I__I I__I__I__I__I__I__I SIOP-Study.-No.

Surname	Prename	Date of birth	Hospital

Result of Randomisation

❒ **Induction I: Carboplatin / Vincristin**

❒ **Induction II: Carboplatin, Vincristin, Etoposide (VP 16)**

Date:_____ Signature:_____

We thank for the registration of your new patient who will receive chemotherapy according to our current study SIOP-LGG-2004.
Please respect the result of randomisation. We had declared our willingness to conduct therapy according to the randomisation at the start of the study. Only in substantiated exceptions this should be changed following consultation of the national study coordinator-

International study office for randomisation:

FAX-Number: