

Dokumentationsbogen: PIOL-R
Studienleiter: Dr. med. Kristoph Jahnke

Version 1.0 vom 16.01.2008

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Nichtinterventionelle, prospektive Registerstudie zur Behandlungspraxis des primären intraokulären Lymphoms in der klinischen Routine (PIOL-R)

DOKUMENTATIONSBOGEN

IDENTIFYING INFORMATION

1. Patient registration number

Patient registration number = [2nd letter of first name] [second letter of last name] – [birth date (mmyy)] – [number of treating center]; see patient registration form (“Meldebogen”) for details.

2. Name of researcher

3. Name of hospital/practice

4. City

5. Country

6. Histological specimen available

PATIENT BASIC INFORMATION, HISTORY AND HISTOLOGY

1. Date of birth (mm/yyyy)

2. Age at diagnosis years

3. Sex

4. Karnofsky performance status at diagnosis %

5. ECOG performance status at diagnosis (only if Karnofsky status is unavailable)

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6. Prior or concomitant malignancies

Please list malignancies

Date of diagnosis (mm/yyyy)

7. Initial symptoms (please list)

8. Duration of symptoms before diagnosis (months)

9. Date of first occurrence of symptoms (mm/yyyy)

10. Date of histologic diagnosis (mm/yyyy)

11. Diagnostic procedure

If you selected "other", please list here

12. Histology of primary intraocular lymphoma (PIOL)

If you selected "other", please list here

DIAGNOSTIC PROCEDURES

1. Serum LDH at diagnosis

2. Slit lamp examination result

3. Pathology result of vitrectomy

4. Pathology result of chorioretinal biopsy

5. Other ocular studies

IL-6/IL-10 ratio

Result

Flow cytometry

Result

PCR

Result

Other studies: please list here

Result

6. CSF cytology

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7. CSF protein mg/dl

8. CSF cell count cells/ μ l

9. Other CSF studies

LDH
Result

Flow cytometry
Result

PCR
Result

Other studies: please list here
Result

10. Brain and/or spine lymphoma at any time point?

11. Diagnostic procedure for brain and/or spine lymphoma
If you selected "other", please list here

12. Date of diagnosis of brain and/or spine lymphoma (mm/yyyy)

FIRST-LINE TREATMENT

1. Surgery of brain and/or spine lymphoma

Surgical extension

Date of surgery for brain and/or spine lesions (mm/yyyy)

2. Corticosteroid administration during treatment for PIOL

Ocular response to corticosteroids

3. Ocular chemotherapy

Drugs for intraocular chemotherapy
If you selected "other", please list here

Drug dose for ocular MTX: mg per cycle
Drug doses for ocular rituximab: mg per cycle
Drug doses for other ocular drugs: mg per cycle

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Start date of ocular chemotherapy (mm/yyyy)

Duration of ocular chemotherapy months
Number of treatment cycles

4. Ocular radiotherapy

Total dose of ocular radiotherapy Gray

Start date of ocular radiotherapy (mm/yyyy)

5. Systemic chemotherapy

MTX
Drug dose for systemic MTX: mg/m²/cycle

Ifosfamide
Drug dose for systemic ifosfamide: mg/m²/cycle

Trofosfamide
Drug dose for systemic trofosfamide: mg/cycle

Rituximab
Drug dose for systemic rituximab: mg/m²/cycle

Cytarabine
Drug dose for systemic cytarabine: mg/m²/cycle

Topotecan
Drug dose for systemic topotecan: mg/m²/cycle

Temozolomide
Drug dose for systemic temozolomide: mg/m²/cycle

Other drugs: please list here
Drug doses for other systemic drugs: mg/m²/cycle

Start date of systemic chemotherapy (mm/yyyy)

Duration of systemic chemotherapy months
Number of treatment cycles

6. Brain/spine radiation therapy

Type of brain/spine radiation therapy

Total dose of brain radiation therapy Gray

Total dose of spine radiation therapy Gray

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Start date of brain/spine radiation therapy (mm/yyyy)

7. Intrathecal chemotherapy

MTX

Drug dose for intrathecal MTX: mg/cycle

Cytarabine

Drug dose for intrathecal cytarabine: mg/cycle

Dexamethasone

Drug dose for intrathecal dexamethasone: mg/cycle

Rituximab

Drug dose for intrathecal rituximab: mg/cycle

Thiotepa

Drug dose for intrathecal thiotepa: mg/cycle

Other drugs: please list here

Drug doses for other systemic drugs: mg/cycle

Start date of intrathecal chemotherapy (mm/yyyy)

Duration of intrathecal chemotherapy months

Number of treatment cycles

8. Overall response of PIOL after chemotherapy (ocular and/or systemic and/or intrathecal):

9. Overall response of PIOL after radiotherapy (ocular and/or brain/spine):

10. Overall response of brain/spine lymphoma after chemotherapy (ocular and/or systemic and/or intrathecal):

11. Overall response of brain/spine lymphoma after radiotherapy (ocular and/or brain/spine):

12. Date of best treatment response of PIOL (mm/yyyy)

13. Date of best treatment response of brain/spine lymphoma (mm/yyyy)

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PROGRESSION/RELAPSE

1. Site of first relapse

Brain
Eyes
Meninges
Spine
Systemic

2. First progression or relapse date of PIOL (mm/yyyy)

3. First progression or relapse date of brain/spine lymphoma (mm/yyyy)

4. Current progression/relapse status of PIOL

5. Current progression/relapse status of brain/spine lymphoma

6. Second-line treatment modality

Ocular chemotherapy
Ocular radiotherapy
Systemic chemotherapy
Intrathecal chemotherapy
Brain and/or spine radiotherapy
Other treatment modalities: please list here

7. Second-line chemotherapy drugs

MTX
Drug dose for systemic MTX: mg/m²/cycle
Drug dose for ocular MTX: mg/cycle
Drug dose for intrathecal MTX: mg/cycle

Ifosfamide
Drug dose for systemic ifosfamide: mg/m²/cycle

Trofosfamide
Drug dose for systemic trofosfamide: mg/cycle

Rituximab
Drug dose for systemic rituximab: mg/m²/cycle
Drug dose for ocular rituximab: mg/cycle
Drug dose for intrathecal rituximab: mg/cycle

Cytarabine

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Drug dose for systemic cytarabine: mg/m²/cycle
Drug dose for intrathecal cytarabine: mg/cycle

Topotecan
Drug dose for systemic topotecan: mg/m²/cycle

Temozolomide
Drug dose for systemic temozolomide: mg/m²/cycle

Thiotepa
Drug dose for intrathecal thiotepa: mg/cycle

Other drugs: please list here
Drug doses for other systemic drugs: mg/m²/cycle

Start date of second-line chemotherapy (mm/yyyy)

8. Second-line brain/spine radiation therapy

Type of brain/spine radiation therapy

Total dose of brain radiation therapy Gray

Total dose of spine radiation therapy Gray

Start date of brain/spine radiation therapy (mm/yyyy)

9. Overall response of PIOL after second-line chemotherapy (ocular and/or systemic and/or intrathecal):

10. Overall response of PIOL after second-line radiotherapy (ocular and/or brain/spine):

11. Overall response of brain/spine lymphoma after second-line chemotherapy (ocular and/or systemic and/or intrathecal):

12. Overall response of brain/spine lymphoma after second-line radiotherapy (ocular and/or brain/spine):

13. Date of best second-line treatment response of PIOL (mm/yyyy)

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14. Date of best second-line treatment response of brain/spine lymphoma
(mm/yyyy)

TOXICITY

Instructions:

- **Toxicity is graded according to the Common Terminology Criteria for Adverse Events v3.0 (CTCAE), please see appendix for details.**
- **If one particular patient had multiple events of one certain type of toxicity, please provide the highest toxicity grade only.**
- **Please leave box blank if there was no toxicity.**

1. Allergic reaction (appendix CTCAE v3.0, page 1)
2. Hemoglobin (appendix CTCAE v3.0, page 4)
3. Leukocytes (appendix CTCAE v3.0, page 4)
4. Neutrophils (appendix CTCAE v3.0, page 4)
5. Platelets (appendix CTCAE v3.0, page 4)
6. Cardiac ischemia/infarction (appendix CTCAE v3.0, page 7)
7. Cardiopulmonary arrest (appendix CTCAE v3.0, page 7)
8. Alopecia (appendix CTCAE v3.0, page 14)
9. Diarrhea (appendix CTCAE v3.0, page 20)
10. Mucositis (appendix CTCAE v3.0, page 24)
11. Nausea (appendix CTCAE v3.0, page 24)
12. Gastrointestinal perforation (appendix CTCAE v3.0, page 26)
13. Gastrointestinal ulcer (appendix CTCAE v3.0, page 28)
14. Vomiting (appendix CTCAE v3.0, page 28)

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15. CNS hemorrhage (appendix CTCAE v3.0, page 30)
16. Gastrointestinal hemorrhage (appendix CTCAE v3.0, page 31)
17. Cholecystitis (appendix CTCAE v3.0, page 34)
18. Pancreatitis (appendix CTCAE v3.0, page 34)
19. Febrile neutropenia (appendix CTCAE v3.0, page 35)
20. Infection (documented clinically) with grade 3 or 4 absolute neutrophil count (see item 4. above)
(appendix CTCAE v3.0, page 35)
21. Infection with normal absolute neutrophil count
(appendix CTCAE v3.0, page 35)
22. ALT (appendix CTCAE v3.0, page 40)
23. AST (appendix CTCAE v3.0, page 40)
24. Bilirubin (appendix CTCAE v3.0, page 40)
25. Creatinine (appendix CTCAE v3.0, page 41)
26. Osteonecrosis (appendix CTCAE v3.0, page 45)
27. CNS ischemia (appendix CTCAE v3.0, page 47)
28. Encephalopathy (appendix CTCAE v3.0, page 48)
29. Leukencephalopathy (appendix CTCAE v3.0, page 49)
30. Memory impairment (appendix CTCAE v3.0, page 49)
31. Mental status (appendix CTCAE v3.0, page 49)
32. Personality (appendix CTCAE v3.0, page 50)
33. Seizure (appendix CTCAE v3.0, page 51)

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- 34. Somnolence (appendix CTCAE v3.0, page 51)
- 35. Cataract (appendix CTCAE v3.0, page 52)
- 36. Glaucoma (appendix CTCAE v3.0, page 52)
- 37. Hypoxia (appendix CTCAE v3.0, page 57)
- 38. Secondary malignancy (appendix CTCAE v3.0, page 63)
- 39. Thrombosis/thrombus/embolism (appendix CTCAE v3.0, page 70)

FOLLOW-UP

- 1. Last follow-up date (mm/yyyy)
- 2. Last status of PIOL
- 3. Last status of brain/spine lymphoma
- 4. Current status
- 5. Date of death (mm/yyyy)
- 6. Cause of death
If you selected "other", please specify here

NOTES

Date: _____ Signature: _____