

Please send the completed CRFs to the Data Center:

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KRANIOPHARYNGEOM Registry 2019 Data at Diagnosis Recording Form

CRF 1

| | | | | |
|------------------|---------|--------|-----------|-----------|
| Patient initials | Pat.nr. | Gender | Birthdate | Malign-ID |
| | | | | |

| | | |
|---------------|------------|--------------|
| Hospital..... | City | Country..... |
|---------------|------------|--------------|

| | |
|-----------------------------------|-------------------------------------|
| Date of diagnosis (Imaging) | Date of diagnosis (Histology) |
|-----------------------------------|-------------------------------------|

Anthropometric data

| | |
|--|---|
| Examination Date: ____:____:____ | Measured body height (cm): ____:____ |
| Measured waist circumference (cm): ____:____ | Measured body weight (kg): ____:____ |
| Birth weight (g): ____:____ | Measured head circumference (cm): ____:____ |
| Pubertal (PH) stage (Tanner): ____ | Gestational age (wk) ____ |
| Body height father (cm): ____:____ | Pubertal (B/G) stage (Tanner) ____ |
| Body height mother (cm): ____:____ | Body weight father (kg): ____:____ |
| | Body weight mother (kg): ____:____ |

Symptoms before diagnosis: CTC-grade:

| | | hospitalization | | duration in month |
|--|--|---------------------------|--------------------------|--------------------------|
| Growth decline: | <input type="radio"/> yes ____ | <input type="radio"/> yes | <input type="radio"/> no | duration: ____ mo |
| Weight gain: | <input type="radio"/> yes ____ | <input type="radio"/> yes | <input type="radio"/> no | duration: ____ mo |
| Polyuria / Polydypsia /DI: | <input type="radio"/> yes ____ | <input type="radio"/> yes | <input type="radio"/> no | duration: ____ mo |
| Neurological findings: | <input type="radio"/> yes ____ | <input type="radio"/> yes | <input type="radio"/> no | duration: ____ mo |
| Headaches: | <input type="radio"/> yes ____ | <input type="radio"/> yes | <input type="radio"/> no | duration: ____ mo |
| Visual disorders: | <input type="radio"/> yes ____ | <input type="radio"/> yes | <input type="radio"/> no | duration: ____ mo |
| Cognitive disturbance: | <input type="radio"/> yes ____ | <input type="radio"/> yes | <input type="radio"/> no | duration: ____ mo |
| Alopecia: | <input type="radio"/> yes ____ | <input type="radio"/> yes | <input type="radio"/> no | duration: ____ mo |
| Skin disorder: (Hypo-/Hyperpigmentation, Ulceration, Teleangiectasia, Induration) | <input type="radio"/> yes ____ | <input type="radio"/> yes | <input type="radio"/> no | duration: ____ mo |
| Fatigue: | <input type="radio"/> yes ____ | <input type="radio"/> yes | <input type="radio"/> no | duration: ____ mo |
| Incidental finding | <input type="radio"/> yes <input type="radio"/> no | | | |

Preoperative endocrine findings:

| | | |
|--|--|---|
| Diabetes insipidus: <input type="radio"/> | Hypocortisolism: <input type="radio"/> | Pubertas tarda: <input type="radio"/> |
| Hypothyroidism: <input type="radio"/> | Hypogonadism: <input type="radio"/> | Pubertas praecox: <input type="radio"/> |
| Growth hormone deficiency: <input type="radio"/> | | Normal: <input type="radio"/> |

| | |
|--|--------------------------|
| Behavioural abnormalities <input type="radio"/> yes | <input type="radio"/> no |
|--|--------------------------|

| | |
|--|--------------------------|
| Hypothalamic syndrome <input type="radio"/> yes | <input type="radio"/> no |
|--|--------------------------|

(food-seeking behaviour/morbid obesity, somnolence/sleep disturbance, temperature instability)

Remarks:**Address/Fax to Data Centre within 3 months**

Date

Stamp

Signature

KRANIOPHARYNGEOM Registry 2019

Radiotherapy Recording Form 1.1 – Treatment Technique

CRF 3

| Date of Birth | Date of Diagnosis=Surgery | Centre ID | Malign-ID |
|---|---|---|---|
| <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> | <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> | <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> | <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> |

 Male Female Initials

 Image fusion (MRI/CT) for treatment planning no yes

 3-D treatment planning no yes

 RT mode Photons Protons Other _____

 RT technique

- Conventional simulation-based XRT
- 3D conformal XRT without intensity modulation
- Intensity-modulated XRT with fixed gantry angles (IMRT)
- Volumetric modulated arc therapy (VMAT)
- Tomography
- Active scanning/ pencil beam scanning (protons)
- Passive scattering/ uniform scanning (protons)
- Fractionated stereotactic radiotherapy
- Radiotherapy
- Brachytherapy
- Daily imaging for set-up
- Other _____

 Target of radiotherapy

- Residual tumor, recurrent/progressive tumor only
- Residual tumor + high risk area
- Total area with initial tumor contact (tumor bed, primary tumor/ recurrent/progressive tumor + residual tumor)

 Volume GTV (residual tumor/ recurrent tumor) (cm³): _____
 not applicable

 Volume GTV (residual tumor + tumor bed) (cm³): _____
 not applicable

 Volume CTV (cm³): _____

Margin GTV-CTV (mm): _____

 Volume PTV (cm³): _____

Margin CTV-PTV (mm): _____

Dose of prescription Total dose: _____ Gy Number of fractions: _____

Single dose: _____ Gy

| Target volume/ risk organs | Uniform name | May (D2%) in Gy | Mean dose in Gy |
|---|--------------------------------------|-----------------|-----------------|
| GTV (residual/progressive tumor) | GTV_res/rel | | |
| GTV (residual tumor + tumor bed) | GTV_res+tb | | |
| CTV | CTV_XXXX (prescribed dose in cGy) | | |
| PTV | PTV_XXXX (prescribed dose in cGy) | | |
| Brainstem | Brainstem | | |
| Brainstem centre (ø 2-3 mm) | Brainstem_Cent | | |
| Spinal cord (below C1) | SpinalCord | | |
| Cochlea (left) | Cochlea_L | | |
| Cochlea (right) | Cochlea_R | | |
| Eye lense (left) | Lens_L | | |
| Eye lense (right) | Lens_R | | |
| Hippocampus (left) | Hippocampus_L | | |
| Hippocampus (right) | Hippocampus_R | | |
| Hypothalamus | Hypothalamus | | |
| Infratentorial brain (posterior fossa) | Brain^Infratent | | |
| Chiasma | OpticChiasm | | |
| Nervus opticus (left) | OpticNrv_L | | |
| Nervus opticus (right) | OpticNrv_R | | |
| Pituitary gland | Pituitary | | |
| Supratentorial brain | Brain^Supratent | | |
| Temporal lobe (left) | Lobe_Temporal_L | | |
| Temporal lobe (right) | Lobe_Temporal_R | | |
| Thyroid gland | Gldn_Thyroid | | |

Remarks:

As part of quality assurance, the RT data set must be sent to Reference Radiation Therapy after the end of irradiation. The dataset should contain the following data: 1. diagnostic imaging (initial and postoperative MR), 2. planning CT, 3. RT structure set, 4. RT image, 5. RT plan for target volumes and contoured risk organs, 6. MR sequences used for contouring, 7. registration matrix of MR fusion.

Please contact the Reference Center Radiation Therapy Essen for submission of the radiation plan in DICOM format:

Westdeutsches Protonentherapiezentrum Essen (WPE)
Referenzzentrum Strahlentherapie Essen
Am Mühlenbach 1
45147 Essen
Tel.: +49 201 723-8156
FAX: 49 201 723-5978
Mail: wpe_referenzzentrum_strahlentherapie@uk-essen.de

Radiation plan sent to the Reference Center Radiation Therapy Essen?

yes no

Date

Stamp

Signature

KRANIOPHARYNGEOM Registry 2019

Consignment bill for sending the radiological imaging to the Radiological Reference Center Augsburg

CRF 4

| | | | |
|---------------|---------------------------|-------------------------------|--|
| Date of Birth | Date of Diagnosis=Surgery | Centre ID | Malig-ID |
| □□ □□ □□□□ | □□ □□ □□□□ | □□□□ | □□□□□□ |
| | | Male <input type="checkbox"/> | Female <input type="checkbox"/> Initials <input type="checkbox"/> <input type="checkbox"/> |
| Hospital..... | | City..... | Country..... |

Only enclose this form when sending CDs by postal mail!

We prefer sending the images to the neurological reference center via **MDPE-Server** (<https://www.mdpe-hit.de/>)! If sending by postal mail, send the CD with Dicom data without viewer to the following address:

Dr. Brigitte Bison,
Diagnostische und interventionelle Radiologie und Neuroradiologie
Universitätsklinikum Augsburg, Stenglinstr. 2,
86156 Augsburg, Tel.: +49 (0)821 4002954; Fax: +49 (0)821 4003312
E-Mail: hit-nrad@uk-augsburg.de

Original images are returned to the centers as soon as possible after scanning/documentation. The reference assessment of the neuroradiological findings is sent to the centers within few working days.

| | | | |
|--------------------------------|--|--|---|
| Multiple answers possible | | | |
| Diagnosis: | _____ | Date of surgery: | □□□□□□□□ |
| Examination: | <input type="radio"/> at first diagnosis | Date of MRI: | □□□□□□□□ |
| | <input type="radio"/> during the course | Date of CT: | □□□□□□□□ |
| Imaging: | CT <input type="radio"/> yes <input type="radio"/> no | <input type="radio"/> without contrast medium (CM) | <input type="radio"/> with contrast medium (CM) |
| | MRI <input type="radio"/> yes <input type="radio"/> no | <input type="radio"/> T1-weighted | <input type="radio"/> with CM |
| | | <input type="radio"/> T2-weighted | <input type="radio"/> without CM |
| Date of shipment: | □□□□□□□□ | | |
| Date of medical report: | □□□□□□□□ | | |
| Images returned: | □□□□□□□□ | | |

Date

Stamp

Signature

KRANIOPHARYNGEOM Registry 2019

Follow-Up Recording Form

CRF 5

Date of Birth

Date of Diagnosis=Surgery

Centre ID

Malig-ID

Male Female Initials

Hospital.....

City.....

Country.....

Anthropometric data

Examination Date:

Measured body height (cm)

 ,

Measured body height (cm)

 ,

Measured body weight (kg)

 ,

Measured head circumference (cm)

 ,

Pubertal (PH) stage (Tanner)

Pubertal (B/G) stage (Tanner)

Symptoms in the course:**CTC-grade:****hospitalization****duration in month**

Growth decline:

 yes yes noduration: mo

Weight gain:

 yes yes noduration: mo

Neurological findings:

 yes yes noduration: mo

Headaches:

 yes yes noduration: mo

Visual disorders:

 yes yes noduration: mo

Cognitive disturbance:

 yes yes noduration: mo

Alopecia:

 yes yes noduration: mo

Skin disorder:

 yes yes noduration: mo

(Hypo-/Hyperpigmentation, Ulceration, Teleangiectasia, Induration)

Fatigue:

 yes yes noduration: mo**Endocrine findings:**

Diabetes insipidus

Hypocortisolism

Puberty:

Pubertas praecox

Hypothyroidism

Hypogonadism

Pubertas tarda

Growth Hormone deficiency

normal

Behavioural abnormalities yes no**Hypothalamic syndrome** yes no

(food-seeking behaviour/morbid obesity, somnolence, sleep disturbance, temperature instability)

Medication:

Minirin/DDAVP:

 yes no

Sex steroids:

 yes no

L-Thyroxine:

 yes no

Psychopharmaceuticals:

 yes no

Growth hormone:

 yes no

Sleep modifying drugs

 yes no

Glucocorticoids:

 yes noothers: **Remarks:**

Address/Fax to Data Centre within 3 months

Date

Stamp

Signature

KRANIOPHARYNGEOM Registry 2019 Status, Relapse and Death

CRF 6

annually, at relapse and/or death

| | | | |
|---------------|---------------------------|-------------------------------|---|
| Date of Birth | Date of Diagnosis=Surgery | Centre ID | Malign-ID |
| □□ □□ □□□□ | □□ □□ □□□□ | □□□ | □□□□□□ |
| | | Male <input type="checkbox"/> | Female <input type="checkbox"/> Initials □□ |

Hospital..... City..... Country.....

Status at follow up

Date of Examination □□□□□□□□

- Status of patient
- Alive - free from tumor
 - Alive with post op residual tumor
 - Relapse after complete resection
 - Progression of residual tumor
 - Dead

comments:

Relapse/progression treatment: Date: □□□□□□□□

- No treatment
- Surgery
 - Complete
 - Subtotal
- Radiotherapy (XRT)
- Cyst drainage
- Ventriculo-perit. Shunt
- Instillation of radioisotopes
 - Phosphorus
 - Yttrium
 - Radium
- Instillation of sclerosing substances (e.g. Interferon α)
- Other _____

Death: Date of death: □□□□□□□□

- Cause:
- Primary tumor disease
 - Relapse/ progression
 - Treatment related mortality
 - Addison's crisis
 - 2nd malignancy
 - cannot differentiate if tumor or treatment
 - Hypopituitarism
 - Cardiovascular cause (eg. strokes)
 - Other cause.....

Remarks:

Address/Fax to Study Centre within 3 month

Date: Stamp: Signature:

Please do not fill out this form – it will be reported by the radiological reference center Augsburg.

KRANIOPHARYNGEOM Registry 2019

Radiological Reference Evaluation Recording Form

CRF7

Date of Birth

Date of Diagnosis=Surgery

Centre ID

Malig-ID

Male Female Initials

Hospital.....

City.....

Country.....

Date of surgery:

Examination:

 at first diagnosis

MRI date:

 during the course

CT date:

Imaging:**CT** yes no without contrast medium (CM) with contrast medium (CM)**MRI** yes no T1-weighted
 T2-weighted with CM
 without CM**Tumor localization** intrasellar intra-extrasellar extrasellar**Tumor structure:** solid cystic mixed**Displacement/Compression of:** Pituitary stalk Thalamus III. Ventricle Ant. Hypothalamus Post. Hypothalamus Opt. chiasm**Hydrocephalus** yes no Lateral ventricles III. Ventricle**max. Tumor-Diameter** (solid and cystic) (mm) based on: MRI-Finding CT-Findings **Total tumor (mm):****Cystic part (mm):**Cranio-caudal Cranio-caudal Ant-posterior Ant-posterior right-left right-left max. midline height **Cystic part > 50 %:** yes no**CT evaluation:**

preoperative:

calcifications

 yes no

during the course

calcifications

 yes no**MRI evaluation (slices <= 3 mm):**Signal T1 hypointense isointense hyperintenseSignal T2 hypointense isointense hyperintense**Overall:****Progression:** yes no**Recurrence:** yes no**Remarks:****Address/Fax to Data Centre within 3 months**

Date

Stamp

Signature

Please send the completed CRFs to the Data Center:

PD Dr. med. Carsten Friedrich, Universitätsklinik für Kinder- und Jugendmedizin, Klinik für Allgemeine Kinderheilkunde, Hämatologie/Onkologie, Klinikum Oldenburg AöR, Rahel-Straus-Str. 10, 26133 Oldenburg, Tel.: +49 (0)441 403707082043, Fax: +49 (0)441 4032789278

KRANIOPHARYNGEOM Registry 2019 CRF 8

Report of serious adverse events Recording Form

| | | | |
|---------------|---------------------------|-------------------------------|---|
| Date of Birth | Date of Diagnosis=Surgery | Centre ID | Malig-ID |
| □□ □□ □□□□ | □□ □□ □□□□ | □□□□ | □□□□□□ |
| | | Male <input type="checkbox"/> | Female <input type="checkbox"/> Initials <input type="checkbox"/> □ |

Hospital..... City..... Country.....

Reporting party / contact person / name: _____

Contact phone number / fax number: _____

Hospital: Date/Signature (Stamp): _____

Adverse events (AEs) are all disturbances of well-being (subjectively perceived as well as objectively ascertainable), symptoms of illness, possibly intercurrent diseases, and impairments leading to accidents occurring during the observation period, irrespective of a possible causal relationship with the study treatment. Expected AEs related to radiotherapy (toxicities) will be recorded on CRF 3; all other AEs will be documented on this form.

Serious adverse events occurring during therapy must be documented and reported immediately, i.e. **within 24 hours**, to the study center in Oldenburg.

AEs classification is based on severity:

- Mild (symptoms that are easily tolerated and do not require a change in approach).
- Moderate (symptoms that are severe enough to limit the patient's ability to perform and require medical intervention).
- Severe (symptoms that are so severe that the patient's performance is limited and he/she cannot perform his/her usual activities, requiring medical intervention, e.g. Addison crisis)

Serious adverse events include:

- Any death, regardless of cause of death.
- Life-threatening/life-threatening medical conditions.
- Events that result in permanent severe disability.
- Overdose events that result in symptoms

Date of Event: ____ . ____ . _____

Exact description of event:

Type, onset, duration, manifestation/severity, causality, actions taken, if any.

Related signs, symptoms, and laboratory changes should be grouped into a single condition.
