Patienten-ID: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**DOKUMENTATIONSBOGEN VISITE V1 / BASELINE**

**Datum Informed consent:\_\_\_\_\_\_\_\_\_\_\_Version:\_\_\_\_\_\_\_\_\_\_\_**

**Kopie ICF an Patienten ausgehändigt?: Ja  Nein**

|  |  |  |
| --- | --- | --- |
| Inclusion Criteria |  |  |
|  | YES | NO |
| Histologically proven adenocarcinoma of the GEJ type II, defined according to the separately provided SOP for screening endoscopies |  |  |
| Non-metastatic tumor, resectable by both transthoracic esophagectomy and transhiatal extended gastrectomy according to the local surgical investigator |  |  |
| Age ≥ 18 |  |  |
| ECOG Eastern Cooperative Oncology Group (ECOG) performance status 0–2 |  |  |
| ASA < 4. |  |  |
| Pre-treatment stage cT1-4a N0/N+, M0 |  |  |
| In case of stage cT4a, curative resectability must be explicitly verified by the local surgical investigator prior to randomization |  |  |
| Patients with locally advanced tumors (T3-T4 or N+) who received four cycles of chemotherapy (FLOT) preoperatively |  |  |
| Negative serum pregnancy test during screening period for women of child-bearing age |  |  |
| Patients with a cardiac history should receive a cardiology consultation and should have a left ventricular ejection fraction > 50% (determined by echocardiography) |  |  |
| Adequate respiratory function (pulmonary function tests only necessary in symptomatic patients) with FEV1>/= 1.5 l/s |  |  |
| Adequate bone marrow function (white blood cells > 3x10^9 /l; hemoglobin > 9 g/dl; platelets > 100x10^9 /l), renal function (glomerular filtration rate >60 ml/min), and liver function (total bilirubin < 1.5x upper level of normal (ULN), aspartate transaminase (AST) < 2.5x ULN and alanine transaminase (ALT) < 3x ULN) |  |  |
| Written informed consent |  |  |

|  |  |  |
| --- | --- | --- |
| Exclusion criteria |  |  |
|  | Ja | Nein |
| Tumors of squamous, adenosquamous or another non-adenocarcinoma histology |  |  |
| Advanced inoperable or metastatic GEJ type II adenocarcinoma |  |  |
| GEJ type II adenocarcinoma staged cT4b, M+ |  |  |
| GEJ type II cT4a evaluated as not curatively resectable by the local surgical investigator |  |  |
| Histologically proven adenocarcinoma of the GEJ type I and III |  |  |
| Severe tumor stenosis preventing endoscopic tumor classification |  |  |
| Tumor expanding more than 5 cm proximal of the GEJ |  |  |
| Tumor resectable only by transthoracic esophagectomy or only by transhiatal extended gastrectomy, according to the local surgical investigator |  |  |
| Positive lymph nodes only resectable by transthoracic esophagectomy (i.e. in the mid-upper mediastinum) or only resectable by transhiatal extended gastrectomy according to the local surgical investigator. |  |  |
| Patients with locally advanced tumors (T3-T4 or N+) who did not receive chemotherapy (FLOT) preoperatively or received more or less than the allowed 4 cycles of chemotherapy |  |  |
| Clinically significant (active) cardiac disease (e.g. symptomatic coronary artery disease or myocardial infarction within last 12 months) |  |  |
| Clinically significant lung disease (forced expiratory volume in one second (FEV1) < 1.5 l/s |  |  |
| Pregnant women and nursing mothers |  |  |
| Persons with any kind of dependency on the principal investigator or employed by the sponsor or principal investigator |  |  |
| Legally incapictated persons |  |  |
| Persons held in an institution by legal or official order |  |  |

SERUM-SCHWANGERSCHAFTSTEST

Untersuchungsdatum: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Ergebnis: positiv negativ

Ggf. Gründe für Fehlen der Untersuchung: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

RANDOMISIERUNG

Hier sollte das Ergebnis der Randomisierung eingeheftet werden.

EORTC-FRAGEBÖGEN

Hier sollten die EORTC-Fragebögen eingeheftet werden. Bitte stellen Sie sicher, dass alle drei Fragebögen ausgefüllt wurden.