Supplement 2: Data extraction sheet

**Identifier:**

**Data Extractor:**  **SB**  **PH**  **AMI Other:**

**Study Identifiers**

**Title:**

**Author:** **Author’s institution:**

**Publication Year:** **Journal name:**

**Volume:** **Page numbers:**

**Language:**  **English**  **other:**

**Trial registered:**  **no**  **yes at:** **Registration number:**

**Conflict of Interest:  stated  not stated**

**Funding:  industry  independent  not stated**

**Sponsor**

**Characteristics of study**

**Study period:**

**recruitment/** **duration from** **to**  **not stated**

**Participating Centres:**

**mono-centre**  **multicentre No. of centres:**

**Participating Countries:**

**national:**  **international:**

**Study Type:**

**Trial Phase:**

**If comparative study, number of treatment groups:**

**two-arm**  **multi-arm no. of arms:**

**Data collection:**  **prospective**  **retrospective**

**Primary endpoint defined:  yes  no**

**Methods**

**Statistics:**

**Sample size calculation: n =       Power:** **% Delta:**  **not stated**

**Analysis strategy:  ITT  PP  other  not stated**

**Patients total: n =**

**Patients evaluable**: **n =** *(for analysis of primary endpoint)*

**Withdrawals: n =**  **not stated**

**Lost to follow-up: n =**  **not stated**

**Risk of Bias Assessment**

**Risk of Bias Tool Cochrane in case of RCTs:**

|  |  |  |
| --- | --- | --- |
| **Bias** | **Judgment** | **Justification** |
| **Random sequence generation (selection bias)** |  |  |
| **Allocation concealment (selection bias)** |  |  |
| **Blinding of participants and personnel (performance bias)** |  |  |
| **Blinding of outcome assessment (detection bias)** |  |  |
| **Incomplete outcome data (attrition bias)** |  |  |
| **Selective reporting (reporting bias)** |  |  |
| **Other bias** |  |  |

**Downs&Black criteria in case of non-RCT (modified for non-RCT):**

|  |  |  |
| --- | --- | --- |
| **Bias** | **Judgment** | **Justification** |
| **Reporting** | | |
| 1. **Is the hypothesis/aim/objective of the study clearly described?** |  |  |
| 1. **Are the main outcomes to be measured clearly described in the Introduction or Methods section?** |  |  |
| 1. **Are the characteristics of the patients included in the study clearly described?** |  |  |
| 1. **Are the interventions of interest clearly described?** |  |  |
| 1. **Are the distributions of principal confounders in each group of subjects to be compared clearly described?** |  |  |
| 1. **Are the main findings of the study clearly described?** |  |  |
| 1. **Does the study provide estimates of the random variability in the data for the main outcomes?** |  |  |
| 1. **Have all important adverse events that may be a consequence of the intervention been reported?** |  |  |
| 1. **Have the characteristics of patients lost to follow-up been described?** |  |  |
| 1. **Have actual probability values been reported (e.g. 0.035 rather than <0.05) for the main outcomes except where the probability value is less than 0.001?** |  |  |
| **External validity** | | |
| 1. **Were the subjects asked to participate in the study representative of the entire population from which they were recruited?** |  |  |
| 1. **Were those subjects who were prepared to participate representative of the entire population from which they were recruited?** |  |  |
| 1. **Were the staff, places, and facilities where the patients were treated, representative of the treatment the majority of patients receive?** |  |  |
| **Internal validity** | | |
| 1. **Was an attempt made to blind study subjects to the intervention they have received?** |  |  |
| 1. **Was an attempt made to blind those measuring the main outcomes of the intervention?** |  |  |
| 1. **If any of the results of the study were based on “data dredging”, was this made clear?** |  |  |
| 1. **In trials and cohort studies, do the analyses adjust for different lengths of follow-up of patients, or in case-control studies, is the time period between the intervention and outcome the same for cases and controls?** |  |  |
| 1. **Were the statistical tests used to assess the main outcomes appropriate?** |  |  |
| 1. **Was compliance with the intervention/s reliable?** |  |  |
| 1. **Were the main outcome measures used accurate (valid and reliable)?** |  |  |
| **Internal validity – confounding (selection bias)** | | |
| 1. **Were the patients in different intervention groups (trials and cohort studies) or were the cases and controls (case-control studies) recruited from the same population?** |  |  |
| 1. **Were study subjects in different intervention groups (trials and cohort studies) or were the cases and controls (case-control studies) recruited over the same period of time?** |  |  |
| 1. **Were study subjects randomised to intervention groups?** |  |  |
| 1. **Was the randomised intervention assignment concealed from both patients and health care staff until recruitment was complete and irrevocable?** |  |  |
| 1. **Was there adequate adjustment for confounding in the analyses from which the main findings were drawn?** |  |  |
| 1. **Were losses of patients to follow-up taken into account?** |  |  |
| 1. **Did the study have sufficient power to detect a clinically important effect where the probability value for a difference being due to chance is less than 5%?** |  |  |

**Diagnosis**

**Tumor entity:**  **AEG I  AEG II  AEG III  SCC  other**

**gastric cancer**

**esophageal cancer (undifferentiated)**

**Subgroup analysis AEG II:  yes  no**

**Diagnostics for tumor localization:  endoscopy  CT  pathology  other**

**Intervention**

**Surgical procedure:  right abdominothor. OE  transhiatal GE**

**total gastrectomy  left abdominothor. OE**

**transhiatale OE  abdominothor. Gastrectomy**

**Lymph node dissection:  D1  D2  not stated other**

**2-field lymphadenectomy:  yes  no  not stated**

**Surgical expertise:**  **resident**  **consultant**  **not stated**

**Oncological expertise:  resident  consultant  not stated  not applicable**

**Patient characteristics**

|  |  |  |  |
| --- | --- | --- | --- |
| **Parameter** | **total** | **Abdomino-thor.** | **Transhiatal** |
| **Age**  Median (range)  Mean (SD)  Not stated |  |  |  |
| **Gender**  Male : female  Not stated | **:** | **:** | **:** |
| **Follow-up (months)**  Median (range)  Mean (SD)  Not stated |  |  |  |
| **ASA** | ASA 1  ASA 2  ASA 3  ASA 4 | ASA 1  ASA 2  ASA 3  ASA 4 | ASA 1  ASA 2  ASA 3  ASA 4 |
| **Comorbidities**  art. HTN (n)  COPD (n)  DM (n)  Smoker (n)  Reflux (n)  Other (n) |  |  |  |
| **Functional status**  ECOG  Karnofsky  Other | yes  no  0  1  2  3  4  5  100%  90%  80%  70%  60%  50%  40%  30%  20%  10%  0% | yes  no  0  1  2  3  4  5  100%  90%  80%  70%  60%  50%  40%  30%  20%  10%  0% | yes  no  0  1  2  3  4  5  100%  90%  80%  70%  60%  50%  40%  30%  20%  10%  0% |
| **Patients included (n)**  Patients randomized (n) if applicab.  Patients withdrawn (n) if applicab.  Patients lost to follow-up (n)  Patients explored (n**)**  Patients resected (n)  Patients evaluated for primary endp. |  |  |  |
| **Tumour stage pathology (auch yp)**  TNM  other:  UICC | pT1  pT2  pT3  pT4  pN0  pN1  pN2  pN3  pNx  pM0  pM1  pMx  I  II  III  IV | pT1  pT2  pT3  pT4  pN0  pN1  pN2  pN3  pNx  pM0  pM1  pMx  I  II  III  IV | pT1  pT2  pT3  pT4  pN0  pN1  pN2  pN3  pNx  pM0  pM1  pMx  I  II  III  IV |
| **Neoadjuvant therapy**  **If yes: radiochemotherapy**  **Chemotherapy**  **Radiotherapy**  **other** | yes  no | yes  no | yes  no |
| **patients neoadj treatment (n) neoadj pat. restaging (n) neoadj pat explored (n) neoadj pat resected (n)** |  |  |  |
|  |  |  |  |

**Comparability at baseline:  affirmed  not affirmed  not stated**

**Reason:**

**Outcomes**

**Primary endpoint:**

|  |  |  |  |
| --- | --- | --- | --- |
| **Outcome** | **Total** | **Abdomino-thor.** | **Transhiatal** |
| **Postoperative morbidity [n]**  Notes: *complications if noted* | (n)        (n)        (n)        (n)        (n) | (n)        (n)        (n)        (n)        (n) | (n)        (n)        (n)        (n)        (n) |
| **Anastomotic leak (n)**  Dx with  Endoscopy  CT / MRI  Other  not stated |  |  |  |
| **Postoperative mortality [n]**  Notes: *e.g. Interval e.g. 30 d post-OP* |  |  |  |
| **R0 resection rate or percent**  n  percent  Not stated |  |  |  |
| **R1 resection rate or percent**  n  percent  Not stated |  |  |  |
| **R2 resection rate or percent**  n  percent  Not stated |  |  |  |
| **Number of dissected lymph nodes (n)**  Mean (SD)  Median (range)  Not stated |  |  |  |
| **Number of positive nodes (n)**  Mean (SD)  Median (range)  Not stated |  |  |  |
| **-> Lymph node ratio** |  |  |  |
| **Lymph node dissection (n)**  Abdominal (n)  Paraesophageal (n)  Upper mediastinum (n) |  |  |  |
| **Positive lymph nodes**  Abdominal (n)  Paraesophageal (n)  Upper mediastinum (n) |  |  |  |
| **Recurrence documented** | **yes**  **no** | | |
| **Recurrence criteria** |  | | |
| **Local recurrence rate**  Mean (SD)  Median (range)  Not stated |  |  |  |
| **Local recurrence**  **endoluminal**  **extraluminal** |  |  |  |
| **Distant recurrence rate**  Mean (SD)  Median (range)  Not stated  Liver  Lung  PC  Lymph node  other |  |  |  |
| **1 year survival**  percent  not stated |  |  |  |
| **2 year survival**  percent  not stated |  |  |  |
| **3 year survival**  percent  not stated |  |  |  |
| **5 year survival**  percent  not stated |  |  |  |
| **Median survival (range)**  not stated |  |  |  |
| **Disease-free survival**  Mean (SD)  Median (range)  not stated |  |  |  |

**Notes:**

|  |  |
| --- | --- |
|  |  |
| *Date* | *Signature* |