ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: May 27, 2020

ClinicalTrials.gov ID: NCT04027543

Study Identification

Unique Protocol ID:	SYSEC-KY-KS-2019-068
Brief Title:	Neoadjuvant Chemotherapy or Chemoradiotherapy in Resectable Oesophageal Carcinoma#NewEC Study#
Official Title:	Clinical Evidence for Association of Neoadjuvant Chemotherapy or Chemoradiotherapy With Efficacy and Safety in Patients With Resectable Esophageal Carcinoma (NewEC Study)
Secondary IDs:	

Study Status

Record Verification:	May 2020
Overall Status:	Completed
Study Start:	November 14, 2018 [Actual]
Primary Completion:	December 1, 2019 [Actual]
Study Completion:	December 1, 2019 [Actual]

Sponsor/Collaborators

Sponsor:	Sun Yat-Sen Memorial Hospital of Sun Yat-Sen University
Responsible Party:	Principal Investigator Investigator: Herui Yao [hyao] Official Title: Principal Investigator Affiliation: Sun Yat-Sen Memorial Hospital of Sun Yat-Sen University
Collaborators:	Guangdong Provincial People's Hospital Massachusetts General Hospital

Oversight

U.S. FDA-regulated Drug:	Yes
U.S. FDA-regulated Device:	No
U.S. FDA IND/IDE:	No
Human Subjects Review:	Board Status: Exempt
Data Monitoring:	Yes
FDA Regulated Intervention:	No

Study Description

Brief Summary: To provide comprehensive efficacy and safety profiles of neoadjuvant chemoradiotherapy (NCRT) versus neoadjuvant chemotherapy (NCT) versus surgery alone in resectable oesophageal carcinoma.

Detailed Description: Neoadjuvant chemotherapy (NCT) or neoadjuvant chemoradiotherapy (NCRT) has been shown to be better than surgery alone in patients with resectable oesophageal carcinoma, but higher quality evidence is needed as new findings have emerged regarding this issue.Previous evidence-based findings and the current guidelines have not established a survival advantage of NCRT over NCT or an acceptable safety profile of the addition of radiotherapy to NCT; whether NCRT or NCT is more effective for the treatment of adenocarcinoma or squamous cell carcinoma of the oesophagus is unclear.This study aims to provide comprehensive efficacy and safety profiles of NCRT versus NCT versus surgery alone in resectable oesophageal carcinoma.

Conditions

Conditions: Radiotherapy Side Effect
Chemotherapy Effect
Oesophageal Carcinoma
Effect of Drugs
Safety Issues

Keywords: Neoadjuvant chemoradiotherapy
Neoadjuvant chemotherapy
Resectable oesophageal carcinoma
Effective
Safety

Study Design

Study Type: Observational

Observational Study Model: Cohort

Time Perspective: Retrospective

Biospecimen Retention: None Retained

Biospecimen Description:

Enrollment: 423 [Actual]

Number of Groups/Cohorts: 3

Groups and Interventions

Groups/Cohorts	Interventions
Neoadjuvant chemoradiotherapy Patients who had chemoradiotherapy before surgery.	Combination Product: Neoadjuvant chemoradiotherapy In most patients, the chemotherapy regimens before surgery were consisted of cisplatin combined with either fluorouracil or taxanes.
Neoadjuvant chemotherapy Patients who had chemotherapy before surgery.	Drug: Neoadjuvant chemotherapy In most patients, the chemotherapy regimens before surgery were

Groups/Cohorts	Interventions
	consisted of cisplatin combined with either fluorouracil or taxanes.
Surgery alone Patients who only had oesophagectomy. Various surgical oesophagectomy methods were used, such as Ivor Lewis, transthoracic, three-hole, transhiatal, and left transthoracic. The appropriate surgical approach for each patient was chosen according to the tumour location, size, and depth.	Procedure/Surgery: Oesophagectomy Various surgical oesophagectomy methods were used, such as Ivor Lewis, transthoracic, three-hole, transhiatal, and left transthoracic,and the appropriate surgical approach for each patient was chosen according to the tumour location, size, and depth.

Outcome Measures

Primary Outcome Measure:

1. Overall survival (OS)
   The OS was calculated as the time from the date of the histologically documented diagnosis to the date of death or the final follow-up.

   [Time Frame: 5 years]

Secondary Outcome Measure:

2. Disease-free survival (DFS)
   DFS was calculated from the date of R0 resection to the date of disease recurrence or death from any cause

   [Time Frame: 5 years]
3. R0 resection rate
   R0 resection was defined as gross disease removed with negative margins (tumour-free resection margin).

   [Time Frame: Baseline]
4. Pathologic complete response (pCR)
   pCR was defined as no evidence of residual tumour cells in the primary site and resected lymph nodes of the operative specimens.

   [Time Frame: Baseline]
5. 30-day postoperative or in-hospital mortality
   [Time Frame: 30 days]

Eligibility

Study Population:	Patients with histologically documented untreated SCC or adenocarcinoma of the oesophagus or gastro-oesophageal junction that was clinically staged as stage I-III (T1-3, N0-1 and M0) as assessed by a contrast-enhanced multislice computed tomography (CT) scan, positron emission tomography, or endoscopic ultrasonography were eligible.
Sampling Method:	Non-Probability Sample
Minimum Age:	18 Years
Maximum Age:	80 Years
Sex:	All
Gender Based:	No
Accepts Healthy Volunteers:	No
Criteria:	Inclusion Criteria:

- Patients with histologically documented untreated SCC or adenocarcinoma of the oesophagus or gastro-oesophageal junction.
- Patients clinically staged as stage I-III (T1-3, N0-1 and M0) as assessed by a contrast-enhanced multislice computed tomography (CT) scan, positron emission tomography, or endoscopic ultrasonography.
- Patients had an Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 2.

Exclusion Criteria:

- Patients had received any previous treatment for oesophageal cancer.
- Patients who were unsuitable for surgery because of comorbidities.
- Patients had evidence of distant metastatic disease by history and physical examination.

Contacts/Locations

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IPDSharing

Plan to Share IPD: No

	The datasets used or analysed during the current study are available from the corresponding author on reasonable request.

References

Citations:	
Links:	
Available IPD/Information:	