

TCTR ID : TCTR20220603001

Overall Recruitment Status : Recruiting

OTHER ID :

Retrospective registration
This protocol was registered after enrollment of the first participant.

Tracking Information

First Submitted Date : 02 June 2022
First Posted Date : 03 June 2022
Last Update Posted Date : 11 April 2024

Title

Public Title : Prospective study of intensive care and enhanced recovery after surgery (ERAS) protocol in patients undergoing upper gastrointestinal surgery
Acronym : ERAS in UGI Surgery
Scientific Title : Prospective study of intensive care and enhanced recovery after surgery (ERAS) protocol in patients undergoing upper gastrointestinal surgery
Sponsor ID/ IRB ID/ EC ID : 888/2561
Registration Site : Thai Clinical Trials Registry
URL : <https://www.thaiclinicaltrials.org/show/TCTR20220603001>
Secondary ID : No Secondary ID

Ethics Review

1. Board Approval : Submitted, approved
Approval Number : Si 119/2019
Date of Approval : 18 February 2019
Board Name : Siriraj Institutional Review board
Board Affiliation : Faculty of Medicine Siriraj Hospital, Mahidol University
Board Contact : Business Phone : 024192667 Ext. No Data
Business Email : siethics@mahidol.ac.th
Business Address : 2 Wang Lang Road Bangkoknoi, Bangkok 10700, Thailand

Sponsor

Source(s) of Monetary or Material Supports : none
Study Primary Sponsor : Faculty of Medicine Siriraj Hospital
Responsible Party : Name/Official Title : Faculty of Medicine Siriraj Hospital
Organization : Faculty of Medicine Siriraj Hospital
Phone : 024192667 Ext. No Data
Email : siethics@mahidol.ac.th
Study Secondary Sponsor : No Study Secondary Sponsor

Protocol Synopsis

Protocol Synopsis : Intensive care and ERAS protocol is a novel perioperative care for surgical patient. The ERAS concept has been successfully applied in many fields of surgery, including gastric and esophageal surgery. We aimed to investigate the short and long term outcomes of ERAS application for Upper GI surgical patients compared with the conventional care.

URL not available

Health Conditions

Health Condition(s) or Problem(s) Studied : Patients diagnosed with diseases of esophagus, esophagogastric junction, and stomach Underwent surgical treatment at Department of Surgery, Faculty of Medicine Siriraj Hospital since Jan 1, 2005
Keywords : Upper GI disease Surgical treatment Esophagectomy Gastrectomy ERAS Conventional care

Eligibility

Inclusion Criteria : Adult patients, aged more than 18 years
Diagnosed with diseases of esophagus, esophagogastric junction, and stomach

Underwent surgical treatment at Department of Surgery, Faculty of Medicine Siriraj Hospital since Jan 1, 2005

Gender : Both

Age Limit : Minimum : 18 Years Maximum : N/A (No limit)

Exclusion Criteria : none

Accept Healthy Volunteers : No

Status

Overall Recruitment Status : Recruiting

Key Trial Dates Study Start Date (First enrollment) : 01 January 2005 Indicate Type : Actual

Completion Date (Last subject, Last visit) : 31 December 2025 Indicate Type : Anticipated

Study Completion Date : 31 December 2029 Indicate Type : Anticipated

Design

Study Type : Observational

Primary Purpose : Treatment

Number of Groups : 2

Study Endpoint Classification : N/A

Sample size

Planned sample size : 422

Actual sample size at study completion :

Observation Group 1

Group name : Conventional care

Group Description : Upper GI surgical patients underwent standard surgical treatment and received the standard conventional perioperative care

Observation Group 2

Group name : ERAS

Group Description : Upper GI surgical patients underwent standard surgical treatment and received the perioperative care according to the ERAS protocol

Outcome

Primary Outcome

1. Outcome Name : Length of hospital stay

Metric / Method of measurement : length of hospital stay, calculated by total days of hospitalization (from admit to discharge)

Time point : admission date to discharge date, reported by median (IQR)

Secondary Outcome

1. Outcome Name : Complication and survival

Metric / Method of measurement : Complication rate reported in number (percent). Survival reported by overall survival and disease free survival

Time point : Postoperative complication defined by complication that occurred within 30 days after surgery. Survival rate will be followed by 5 years after treatment

Location

Section A : Central Contact

Central Contact First Name : Thammawat Middle Name : Last Name : Parakonthon
Degree : MD Phone : 024198005 Ext. : No Data Email : t.parakonthon@gmail.com

Central Contact Backup First Name : Thikhamporn Middle Name : Lastname : Tawantanakorn
Degree : MD Phone : 024198005 Ext. : No Data Email : Ammy_thi@hotmail.com

Section B Facility Information and Contact

1. Site Name : Faculty of Medicine Siriraj Hospital, Mahidol University
City : Bangkoknoi State/Province : Bangkok Postal Code : 10700
Country : Thailand Recruitment Status : Recruiting

Facility Contact First Name : Thammawat Middle Name : Last Name : Parakonthon
Degree : MD Phone : 024198005 Ext. : No Data Email : t.parakonthon@gmail.com

Facility Contact Backup First Name : Thikhamporn Middle Name : Last Name : Tawantanakorn
Degree : MD Phone : 024198005 Ext. : No Data Email : Ammy_thi@hotmail.com

Investigator Name First Name : Thammawat Middle Name : Last Name : Parakonthon
Degree : MD Role : Principal Investigator

Section C : Contact for Public Queries (Responsible Person)

First Name : Thammawat Middle Name : Last Name : Parakonthon
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Postal Address : Department of Surgery, Faculty of Medicine Siriraj Hospital 2 Wang Lang Road Bangkoknoi
State/Province : Bangkok Postal Code : 10700
Country : Thailand Official Role : Study Principal Investigator
Organization Affiliation : Faculty of Medicine Siriraj Hospital, Mahidol University

Section D : Contact for Scientific Queries (Responsible Person)

First Name : Thammawat Middle Name : Last Name : Parakonthon
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Postal Address : Department of Surgery, Faculty of Medicine Siriraj Hospital 2 Wang Lang Road Bangkoknoi
State/Province : Bangkok Postal Code : 10700
Country : Thailand Official Role : Study Principal Investigator
Organization Affiliation : Faculty of Medicine Siriraj Hospital, Mahidol University

Deidentified Individual Participant-level Data Sharing

Plan to share IPD : No
Reason : Prohibited from laws

Publication from this study

MEDLINE Identifier : No Data
URL link to full text publication : No Data
