PROTOCOL SUBMISSION FORM – Paper Version for Preparation

ISLSsg.org Study Groups Platform

Version 1.6

Primary Investigator:

SALUTATION, FULL NAME AND DEGREES	INSTITUTION / DEPARTMENT, CITY & COUNTRY	EMAIL
E.g. Prof Deniz Balci, MD, PhD	E.g. Ankara University, HPB Surgery, Turkey	E.g. email@email.com

Please include above the details of the Primary Investigator of this study.

List of Co-Investigators / Collaborators:

SALUTATION, FULL NAME AND DEGREES	INSTITUTION / DEPARTMENT, CITY & COUNTRY	EMAIL
E.g. Prof Deniz Balci, MD, PhD	E.g. Ankara University, HPB Surgery, Turkey	E.g. email@email.com

You may add additional collaborators (max 100). For every collaborator we will create an account with ISLSsg.org and they will be able to view and edit your study protocol.

STUDY DETAILS:

Study Title

Indicate the study's design with a commonly used term in the title or the abstract

Summary / Abstract

Provide here an informative and balanced summary of what will be done and how.

Introduction

Background/rationale

Explain the scientific background and rationale for the investigation to be conducted. Consider reporting on what is known, what is not known?

Objectives

State specific objectives, including any prespecified hypotheses

Methods

Study design

Present key elements of study design

Setting

Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection. Include center eligibility criteria.

Participants

Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up.

Variables

Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable. ***Below, you will have the option to upload your excel file of all the list of variables associated to your study in the form of an Excel file****.*

List of Variables / Case Report Form Upload (optional, online version only)
Please optionally prepare your list of variables preferably in excel format or the Case Report Form (CRF) in word or PDF format. By submitting your list of variables or CRF with your protocol, we will create and electronic CRF for you and all your collaborators to help with a more easy, secure, and complete data collection. Please include the variable names, allowed values, and which ones should be mandatory or not to complete the submission of each case.

Data sources/measurement (optional)

For each variable of interest, give sources of data and details of methods of assessment (measurement)

Bias (optional)

Describe any efforts to address potential sources of bias

Study size

Explain how the study size will be arrived at.

Quantitative variables (optional)

Explain how quantitative variables will be handled in the analyses. If applicable, describe which groupings will be chosen and why.

Statistical methods

Describe all statistical methods, including those to control for confounding. Describe any methods to examine subgroups and interactions. Explain how missing data will be addressed. If applicable, explain how loss to follow-up will be addressed. Describe any sensitivity analyses if applicable.

Discussion (optional)

Impact: Discuss the potential clinical impact/significance of the study considering the study objectives and limitations. Limitations: Discuss potential limitations of the study, taking into account sources of potential bias or imprecision (optional).

Message to the Scientific Committee of ISLS

Please provide the Scientific Committee with a short cover letter regarding your study and protocol submission.

Protocol Submission

Please submit your study protocol online, after logging in to ISLSsg.org with your account username and password provided to you, at: ***https://islssg.org/form/protocol-submission***