

Protocol Title: Evaluation of the Impact of a Forward Viewing Scope at Time of ERCP Protocol
Version: 1.2 09/15/2022
MGB IRB Protocol: 2022P001825 (Initial Approval 9/26/2022; Most Recent Approval: 6/6/2024)
NCT #: NCT05627882
PI: Marvin Ryou, MD
Funder: Boston Scientific

ATTACHMENTS:

Statistical Analysis Plan – 9/15/2022

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Statistical Analysis Plan – 9/15/2022:

Based on retrospective data, we assumed a 19% miss rate by a side viewing exam compared to forward viewing exam.¹ With 80% power, 144 patients were required to detect statistical significance. Continuous data were compared using two-sample t-test or Wilcoxon rank-sum test and categorical data using Fisher's exact test. Univariate and multivariable analyses were performed using logistic regression to determine significant predictors of missed findings (i.e., patient characteristics). Statistical significance was defined as a two-tailed P value <0.05. Statistical analysis was performed using SAS 9.4. This trial is registered NCT: NCT05627882.

1. Thomas A, Vamadevan AS, Slattery E, et al. Performing forward-viewing endoscopy at time of pancreaticobiliary EUS and ERCP may detect additional upper gastrointestinal lesions. *Endosc Int Open* 2016;4:E193-7.