Statistical analysis Plan

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Trial registration: ClinicalTrials.gov ID: NCT03457909

Study outcomes

Primary outcome is the success rate of DS-MCE. Secondary outcomes include safety, discomfort associated with the procedure, diagnostic accuracy, image quality and Z-line visualization. All patients will be followed up to 2 weeks to confirm capsule excretion and any adverse events. Any discomfort during the procedure is evaluated with the Ramirez system and our previous system, on a scale from 0 to 3 (0, no; 1, mild/minimal; 2, moderate; and 3, severe/very difficult). Overall discomfort is scored on a scale of 0 to 10 (0, no discomfort; 10, the overall discomfort of EGD). Also, subjects will be asked the preference of DS-MCE and EGD. The diagnostic accuracy of DS-MCE is assessed by esophageal diagnosis and grade of reflux esophagitis and esophageal varices in comparison to EGD. Reflux esophagitis and esophageal varices identified during EGD and DS-MCE are classified using the Los Angeles classification, Baveno III consensus and DFC.

The bubble grade ranges from 0 to 3 (0, no bubble; 1, a few bubbles; 2, increased amount of bubbles; 3, severe bubbles). Image quality grade ranges from 1 to 10 (1, the worst quality; 10, the quality of the image captured by EGD).

Statistical analysis

Quantitative data (age, comfort assessment, image quality) are summarized with the mean (range) and the median (range), while categorical data (sex, success rate of DS-MCE) are presented as frequency (percentage). The diagnostic accuracy is analyzed by fourfold table.