

# **Detachable string magnetically controlled capsule endoscopy for completely viewing the esophagus and stomach: study protocol for a self-controlled single-center study**

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**Trial registration: ClinicalTrials.gov ID: NCT03457909**

## **Objective**

Esophageal capsule endoscopy (ECE) was reported not accurate enough to replace EGD as the passive passage of ECE through the esophagus precluded a thorough investigation. We developed a modified capsule endoscopy, called detachable string magnetically controlled capsule endoscopy (DS-MCE) and performed a pilot study to assess the feasibility and safety of DS-MCE.

## **Study design**

This study is a prospective, single-centered pilot study. The study protocol has been approved by the institutional review board of Changhai Hospital (Second Military Medical University, Shanghai, China).

## **Study patients**

Healthy volunteers and patients with suspected esophageal diseases will be prospectively enrolled in Changhai Hospital from March 2018 to June 2018. Patients with any MCE contradictions will be excluded.

## **Study intervention**

After enrollment, each subject will first undergo DS-MCE, and subsequently EGD within one week. DS-MCE will be performed by an endoscopist (W.Z.) with an experience of > 500 cases of MCE operation. Another endoscopist (W.B.Z.) who is blinded to the DS-MCE diagnosis will perform the EGD examinations and interpret the images. EGD examination are carried out under topical pharyngeal anesthesia induced by a

single oral dose of 100 mg dyclonine hydrochloride.

### **Capsule endoscopy devices and procedure**

Procedures are performed using the NaviCam magnetic capsule guidance system (Ankon Technologies, Shanghai, China). The DS-MCE system consists of two parts, a thin and transparent latex sleeve with an 80cm long hollow string attached to its cauda end and a sterile syringe for single use. The capsule partially enclosed in the sleeve can be detached from the string system through injecting air into the hollow string with the syringe. In a left lateral position, subjects swallow the capsule with water, without any sedation. The capsule is allowed to travel down approximating the gastric cardia, from where the string is slowly pulled up to inspect the esophagus under the guidance of real-time viewing. Images are captured at a rate of 2 frames per second. Target areas of interest can be observed repeatedly. If bubbles obscure the view, subjects are instructed to sip a little water until the esophageal image improved. After completing the esophagus examination, the string is separated from the capsule through injecting 5 ml air with the syringe, taken out of the mouth and discarded, while the capsule entered the stomach with additional water ingestion. Stomach examination and small bowel examination (if needed) are carried out according to standardized protocol.

### **Study outcomes**

Primary outcome is the success rate of DS-MCE, a composite outcome defined as the success rate of completely viewing the esophagus (from the capsule being swallowed, the esophagus observed retrograde, to the string being pulled out after separating from the capsule), detachment of string and capsule at the end of esophageal examination and entering the stomach. 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.

All the images obtained by DS-MCE are monitored in real time and capsule findings were documented by an experienced endoscopist (X.L.). Another endoscopist (X.J.) independently graded Z-line viewing (the number of quadrants captured on the Z-line), image quality and the air bubbles with our previous system. 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).

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