

Title Page

Official title: Clinical Study Protocol

NCT number: NCT03815136

Date: Oct 31, 2019

Protocol

Study title: The Effectiveness of Improved Use of Chewing Gum in Influencing Capsule Endoscopy Transit Time - a Prospective Randomized, Controlled Pilot Study.

Approval date: Oct 25, 2018

Study description:

Brief Summary: The purpose of this study is to determine the effect of chewing gum, during the first one hour of examination in patients undergoing CE for GTT and SBTT time and the proportion of cases with complete small bowel examination and gastroscopy intervention.

Detailed Description: The subjects will include patients who need to a capsule endoscopy (CE) in this unit. We will include 200 patients who had a CE at our centre based on the gastric transit times. These will be randomly divided into two groups. The patients (chew chewing gum) and the controls (do not chew chewing gum). (Capsule endoscopy type: PillCam SB2)

Study Time:

Start: January 31, 2019

Primary Completion: June 30, 2019

Study Completion: July 31, 2019

Eligibility criteria:

Inclusion Criteria: Patients aged ≥ 16 years and < 80 years old presenting for capsule endoscopy. Obtained of written informed consent before the procedure.

Exclusion Criteria: Patients on motility enhancing and/or slowing drugs (narcotics/prokinetics) should stop these at least 5 days prior to the procedure. Patients, who have proven or suspected obstruction of the bowel. Patients, who have had prior small bowel and/or gastric surgery. Patients, who have a dysphagia prohibiting. Patients with diabetes mellitus and/or hypo-/hyper-thyroidism.

Arms and Interventions:

Arms:

Chewing Gum: The subject group will chew sugarless chewing gum for a specific amount of time while undergoing capsule endoscopy. Subjects chewed one piece of gum for approximately 15 min every 30 min at the first hour of the examination.

Control: The control group will not chew chewing gum while undergoing capsule endoscopy.

Assigned Interventions:

Chewing Gum: Patients of chewing gum group chewed one piece of sugarless gum

for approximately 15 min every 30 min at the first hour of the examination.

Control: The control group will not chew chewing gum while undergoing capsule endoscopy.

Participants' information: Sex, Age, BMI, Examination reason.

Outcomes:

Primary Outcome Measure:

Gastric transit time (GTT): The time interval between the first gastric image and the first duodenal image.

Small bowel transit time (SBTT): The time interval between the first duodenal images and the first caecal image.

Secondary Outcome Measure:

Completion rate (CR): The capsule reaching the caecum.

Diagnostic yield (DY): The total number of positive (diagnostic and suspicious) findings.

Intervention rate: Gastroscopy intervention after capsule endoscopy not through pylorus within 1 hour.

Randomization:

Computer-generated random numbers.

Statistical analysis:

Descriptive statistics were used for the baseline characteristics of the participants. Continuous variables were expressed as mean \pm SD, and compared using the Student t-test, while categorical variables were expressed as percentages and counts, and compared using the χ^2 test for categorical variables.