

APPENDIX A

WHO Trial Registration dataset

Data category	Information
Primary registry and trial identifying number	ClinicalTrials.gov. Identifier NCT05700981.
Date of registration in primary registry	17 January, 2023
Secondary identifying numbers	S-20210127, 22/43235
Source(s) of monetary or material support	The Centre for Clinical Implementation of Capsule Endoscopy (CICA)
Primary sponsor	The Centre for Clinical Implementation of Capsule Endoscopy (CICA)
Contact for public queries	TBM [Thomas.bjoersum-meyer@rsyd.dk]
Contact for scientific queries	TBM [Thomas.bjoersum-meyer@rsyd.dk] Odense University Hospital, Department of Surgery
Public title	Sammenligning af kamerakapselundersøgelse og kikkertundersøgelse efter tilfælde med betændelse ved udposninger på tyktarm.
Scientific title	Colon capsule endoscopy compared to conventional colonoscopy in patients with colonic diverticulitis: a randomised controlled superiority trial (CACODI trial)
Countries of recruitment	Denmark
Health condition(s) or problem(s) studied	Diverticulitis, patient satisfaction, colorectal neoplasia
Intervention(s)	Intervention group: colon capsule endoscopy Comparison group: colonoscopy
Key inclusion and exclusion criteria	Ages eligible for study: ≥ 18 years Sexes eligible for study: both Accepts healthy volunteers: no Inclusion criteria: adult patient (≥ 18 years), in-hospital CT-verified diverticulitis. Exclusion criteria: Imaging of the colonic mucosa within the last 12 months and, colonic CT findings that require biopsy (suspected cancer) or polyp removal, CT-verified stenosis in the gastrointestinal tract, cardiac pacemaker, renal insufficiency, pregnancy/breastfeeding, allergies towards active substances administered in the trial, unable to provide oral and written informed consent.
Study type	Interventional Single-centre randomised, controlled trial
Date of first enrolment	February 2023
Target sample size	120
Recruitment status	Recruiting
Primary outcome(s)	Comparison of colonoscopy and colon capsule endoscopy regarding patient satisfaction and tolerance during the bowel preparation, during the diagnostic procedure and 4 weeks after the procedure.
Key secondary outcomes	Comparison of colonoscopy and colon capsule endoscopy regarding completion rate of investigations, the prevalence of diverticula, polyps, cancers and other abnormal findings. Reporting of the number of patients referred to a subsequent colonoscopy after colon capsule endoscopy.
Protocol version and date	Protocol version no. 2, approval date 7 October 2021