

Cash (TOPAZ study)	2021	Gut	USA	Multicentre, prospective, randomised study	Allocation The TOPAZ study was designed to compare the performance of the PBCan C200+ CCE device with CTC in an average risk CRC screening population	Enrollment criteria Eligible subjects between 50 and 75 years of age (African Americans, 45–75 years of age) classified as average risk for CRC and willing and able to participate in the study procedures were included.	Patients included (excluded) 320 (288)	Age, mean, years 65.7 years (SD ±5.68)	Adequate bowel preparation (%) 84.1% of CCE subjects and 95.1% of CTC subjects	Complete 75 (70%)	Method After obtaining informed consent, subjects were randomised 1:1 to receive CRC screening by either CCE or CTC. Bowel preparation was performed using an interactive Web Response System. Investigators were unaware of the randomisation schedule until they randomised a patient.	Key result The proportion of subjects with any polyp ≥6 mm confirmed by histology was 18.4% in CCE versus 18.0% in CTC. Non-inferiority for identification of polyps ≥10 mm was confirmed (relative risk 0.99, 95% CI 0.45 to 2.09). The diagnostic yield of polyps ≥10 mm was 95.0% versus 98.3% in CCE and CTC, respectively. The sensitivity and specificity of CCE for polyps ≥10 mm was 75.4% and 98.3%, while that of CTC was 26.8% and 98.9%. The sensitivity and specificity of CCE for polyps ≥6 mm was 85.8% and 98.2% compared with 50% and 99.1% for CTC. Both tests were well tolerated.	Conclusion CCE was superior to CTC for detection of polyps ≥10 mm and non-inferior for identification of polyps ≥6 mm. CCE should be considered comparable or superior to CTC as a colorectal neoplasia screening test, although neither test is as effective as OC.	Link Cash R, D. Pishier M, R. Fern S, Rajan E, Holtbrook R, Rasmussen D, M., ... Rex D. K. (2020). Multicentre, prospective, randomised study comparing the diagnostic yield of colon capsule endoscopy versus CT colonography in a screening population (the TOPAZ study). <i>Gut</i> , <i>gutjg-2020-325278</i> . doi:10.1136/gutjg-2020-325278	
Deding	2020	United European Gastroenterology	Denmark	Prospective paired study	Investigate relative sensitivity of CCE compared with CTC following incomplete OC. Investigate the completion rate when combining results from the incomplete OC and CCE, and develop a forward-tracking algorithm ensuring a valid completeness of combined information.	Patients with indication for CTC following incomplete OC	105 (97)	NA	76	68	Patients with indication for CTC following incomplete OC were included for CCE and CTC. Location of CCE detection and OC detection were registered to identify complete combined investigations. A based algorithm for localisation of capsules were developed. A based algorithm was developed.	Including CCEs which reached most oral point of incomplete OC. 75 (70%) had complete colon investigations. 78 (80%) had complete colon investigations. Relative sensitivity of CCE compared with CTC was 2.87 (95% confidence interval [CI] 1.14 to 6.94) for overall complete investigation. For polyps ≥5 mm, CCE was 85.7% and 98.2% compared with 50.0% and 99.1% for CTC. Both tests were well tolerated.	Sensitivity of CCE following incomplete OC was superior to CTC. Introducing and improving algorithm-based localisation of capsule detection may increase identification of small complete investigations. United European Gastroenterol J. 2020 Aug;7(162):789-801. 10.1177/2050666220975930. PMID: 32771811. PMCID: PMC7435900.	Deding U, Herp J, Hvidtøft AL, Kobæk-Larsen M, Bujs MM, Nedim ES, Baarug G. Colon capsule endoscopy versus CT colonography after incomplete colonoscopy: Application of artificial intelligence algorithms to identify complete colonic investigations. <i>United European Gastroenterol J</i> . 2020 Aug;7(162):789-801. 10.1177/2050666220975930. PMID: 32771811. PMCID: PMC7435900.	
Gonzalez-Suarez	2020	BMC Med	Spain	Prospective, single-centre, randomised trial	Compare CCE and CTC for the identification of patients with colorectal neoplasia among participants in a CRC screening programme with positive faecal immunochemical test (FIT).	Individuals with a positive FIT result (≥ 20 µg of haemoglobin of faeces) from the population-based, organised CRC screening programme of Barcelona.	340 (295)	60	82	82	Patients were randomised to CCE or CTC before colonoscopy. Endoscopies were blinded to the results of CCE and CTC. Outcome was to compare the performance of CCE and CTC in detecting patients with neoplastic lesions. Included (excluded) by group: 173 (147) in the CCE group and 176 (153) in the CTC group.	In the intention-to-screen analysis, sensitivity, specificity and positive and negative predictive values for the identification of individuals with colorectal neoplasia were 98.1%, 76.8%, 93.3% and 92.0% in the CCE group and 64.8%, 85.7%, 86.8% and 97.7% in the CTC group. In terms of detecting significant neoplastic lesions, the sensitivity of CCE and CTC was 98.1% and 79.3%, respectively. Detection rate for advanced colorectal neoplasia was higher in the CCE group than in the CTC group (100% and 93.1%, respectively; RR = 1.07, <i>p</i> = 0.08). Both CCE and CTC identified all patients with cancer. CCE detected more patients with any lesion than CTC (98.6% and 81.0%, respectively; RR = 1.22, <i>p</i> = 0.002).	Although both techniques seem to be similar in identifying patients with advanced colorectal neoplasia, CCE is more sensitive for the detection of any neoplastic lesion. No significant differences in terms of patients' acceptance and adverse events between both strategies. CCE may benefit from a higher sensitivity for detecting small, flat, sessile and serrated lesions. CTC more specific CCE (98.1% CCE could not be evaluated in 18.3% of patients due to incomplete studies, higher than expected drop out rate in both screening strategies may have contributed to the lack of a significant difference vs. 88.2%, respectively) in identifying significant neoplastic lesions.	Gonzalez-Suarez B, Pleguez M, Araya LK, et al. Colon capsule endoscopy versus CT colonography in FIT-positive colorectal cancer screening subjects: a prospective randomised trial—the VICCA study. <i>BMC Med</i> 18, 255 (2020). https://doi.org/10.1186/s12916-020-01717-4	https://pubmed.ncbi.nlm.nih.gov/32943036/
Utani	2019	Digestion		Multicenter prospective study	Evaluate the performance of CCE and CTC for the identification of non-polypoid (flat) tumors ≥ 2 mm	Patients referred for endoscopic submucosal dissection of polypoid tumors measuring ≥20 mm were enrolled.	30 (27)	NA	NA	85	Patients first underwent CCE, then colonoscopy (performed separately) and CTC on the same day. An experienced gastroenterologist in a third hospital evaluated the CCE and recorded the location, size and morphology of all lesions detected. Blinded to the colonoscopy findings, An experienced radiologist read the CTC under the same conditions. Colonoscopies were defined as the reference.	A total of 30 lesions in 27 patients were assessed. Non-polypoid tumors tend to be depicted as polypoid on CCE. Per patient endoscopies were 8.9 (24/27) for CCE and 0.71 (1/27) for CTC (<i>p</i> = 0.023, McNemar), and per lesion sensitivities were 0.87 (26/30) and 0.87 (26/30) respectively (<i>p</i> = 0.048). Most lesions missed by both modalities were located in the proximal colon. Per lesion sensitivity for CCE was 87%, higher than that of CTC which was 67% (9/14).	Utani K, Kasai S, Matsuda T, Mizusaki K, Fujita T, Nemoto	https://pubmed.ncbi.nlm.nih.gov/31124522/	
Pioche	2017	Endoscopy	France	Randomized trial	Compare video capsule endoscopy (VCE) and computed tomography colonography (CTC) in terms of participation rate and detection outcomes when offered to patients with a positive pFOBT who did not undergo the recommended colonoscopy	Patients with a positive guaiac fecal occult blood test (pFOBT) ≥	NA	NA	NA	NA	An invitation letter offering CTC or VCE was sent to selected patients after randomization. Acceptance of the proposed (or alternative) procedure and procedure results were recorded. Sample size was evaluated according to the hypothesis of a 13 % increase of participation with VCE.	A total of 788 patients were targeted. Following the invitation letter, 510 (159/778) of patients underwent the proposed VCE and 7.4 % (29/378) underwent CTC. (<i>P</i> = 0.18). Following the letter, 8.9 (24/27) for CCE and 0.71 (1/27) for CTC (<i>p</i> = 0.023, McNemar), and per lesion sensitivities were 0.87 (26/30) and 0.87 (26/30) respectively (<i>p</i> = 0.048). Most lesions missed by both modalities were located in the proximal colon. Per lesion sensitivity for CCE was 87%, higher than that of CTC which was 67% (9/14).	Pioche M et al. Colon capsule versus computed tomography colonography for colorectal cancer screening in patients with positive fecal occult blood test who refuse colonoscopy: a randomised trial. <i>Endoscopy</i> 2018; 50(5):761-769	https://pubmed.ncbi.nlm.nih.gov/29486502/	
Spada	2015	Gut	Italy	Prospective comparative trial (subfitted)	Compare colon capsule endoscopy (CCE) and CT colonography (CTC) in a prospective cohort of patients with incomplete colonoscopy	Patients with incomplete colonoscopy	100 (97)	60	83	98	Conservative patients with a previous incomplete colonoscopy underwent CCE and CTC followed by colonoscopy in case of positive findings or other test (polyps/lesions ≥6 mm). Clinical follow-up was performed in the other cases to rule out missed cancer. CTC was performed after colon capsule insertion to 10–12% participation. Since the gold standard colonoscopy was performed only in positive cases, diagnostic yield and positive predictive values of CCE and CTC were used as study end-points.	CCE detected at least one 10mm polyp in 24 patients, while CTC detected at least one 10mm polyp in 12 patients, resulting in a significantly improved relative sensitivity of 2.1 for CCE. CCE detected at least one 20mm polyp in five patients, while CTC detected at least one 20mm polyp in five patients, resulting in a relative sensitivity of 1.87 in favor of CCE. Positive predictive values for polyps ≥10mm and ≥20mm were 80% and 85.7%, respectively, for CCE and CTC, respectively. No missed cancer occurred at clinical follow-up of a mean of 20 months.	Spada C, et al. Colon capsule versus CT colonography in patients with incomplete colonoscopy: a prospective, comparative trial. <i>Gut</i> 2015; 64(2): 272-81.	https://doi.org/10.1136/gut.2014.302222	
Rondinelli	2014	Clinical Gastroenterology and Hepatol Italy		Interventional (Clinical Trial)	We compared the accuracy of CCE and CTC in identifying individuals with at least 1 polyp greater than 6 mm and subjects' attitude toward the procedures.	Positive results from the immunochemical fecal occult blood test (FOBT-positive)	50	59	70	90	Participating individuals underwent CCE, CTC, and OC. The procedures were scheduled as follows: first, the patient underwent the CCE, and, about 15 days later, the patient underwent CTC only in the morning, followed by OC later that day. In a per-patient analysis, the accuracy of CCE and CTC were assessed for individuals with at least 1 polyp 6 mm or larger. Individuals were asked to choose which procedure they would be willing to repeat between CTC and CCE.	The combination of OC, CTC, and CCE identified 16 cases with at least 1 polyp 6 mm or larger (reference standard). CTC identified the polyps with 88.2% sensitivity, 84.8% specificity, a 3.0 positive likelihood ratio, and a 0.57 negative likelihood ratio. CCE identified the polyps with 88.2% sensitivity, 87.8% specificity, a 3.75 positive likelihood ratio, and a 0.58 negative likelihood ratio. Thirty-nine subjects (78%) said they preferred CCE to CTC.	OC and CTC detect polyps 6 mm and larger with high levels of accuracy; these techniques are effective in selecting FOBT-positive individuals who do not need to be referred for colonoscopy. CCE seems to be better tolerated than CTC, and could be a reliable alternative to CTC for FOBT-positive individuals who are unable or unwilling to undergo OC.	Rondinelli E, Borghi C, Mondelli G, et al. Accuracy of capsule endoscopy and computed tomographic colonography in individuals with positive results from the fecal occult blood test. <i>Clin Gastroenterol Hepatol</i> . 2014;12(8):1300-10.	https://pubmed.ncbi.nlm.nih.gov/24388064/