

# BMJ Open Endoscopic mucosal resection using cold snare versus hot snare in treatment for 10–19 mm non-pedunculated colorectal polyps: protocol of a non-inferiority randomised controlled study

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## ABSTRACT

**Introduction** Cold polypectomy has the advantages of simple operation, less time-consuming and fewer complications. Guidelines have recommended cold snare polypectomy (CSP) to resect small polyps sized  $\leq 5$  mm and sessile polyps sized 6–9 mm. However, evidence is scarce regarding cold resection for non-pedunculated polyps sized  $\geq 10$  mm. Cold snare endoscopic mucosal resection (CS-EMR) combining CSP and submucosal injection was designed to improve the complete resection rate and reduce adverse events. We hypothesise that CS-EMR is non-inferior to conventional hot snare endoscopic mucosal resection (HS-EMR) in the resection of 10–19 mm non-pedunculated colorectal polyps.

**Methods and analysis** This study is a prospective, randomised, open-label, non-inferiority, single-centre trial. Outpatients scheduled to undergo a colonoscopy and present eligible polyps will be randomised to receive either CS-EMR or HS-EMR. The primary endpoint is the complete resection. Considering that HS-EMR of 10–19 mm colorectal polyps will yield a complete resection rate of at least 92% and a non-inferiority margin of  $-10\%$ , a total of 232 polyps will be included (one-sided  $\alpha$ , 2.5%;  $\beta$ , 20%). The analyses are intended to evaluate first non-inferiority (lower limit 95% CI greater than  $-10\%$  for group difference) and then superiority (lower limit 95% CI  $> 0\%$ ) if non-inferiority is achieved. Secondary endpoints include en-bloc resection, the occurrence of adverse events, the use of endoscopic clips, resection time and cost.

**Ethics and dissemination** The study has been approved by the institutional review board of the Peking Union Medical College Hospital (No. K2203). All participants in the trial will provide written informed consent. The results of this trial will be published in an open-access way.

**Trial registration number** NCT05545787.

## INTRODUCTION

Colorectal cancer is one of the most common malignant tumours worldwide. According to Global Cancer Statistics 2020, the incidence of colorectal cancer ranks third, and mortality ranks second.<sup>1</sup> According to data

## STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ Randomisation is stratified by polyp size (10–14 mm or 15–19 mm).
- ⇒ The use of electrocautery may affect the pathological interpretation of polyp margins.
- ⇒ Follow-up colonoscopies to assess for polyp recurrence may not be performed due to dropouts.

from the National Cancer Center of China in 2016, the incidence of colorectal cancer ranks second, and mortality ranks fourth in China.<sup>2</sup> Colorectal polyps are the main precancerous lesions of colorectal cancer, and endoscopic polypectomy effectively reduces the incidence and mortality of colorectal cancer.<sup>3</sup>

According to the size, shape, location and pathological type of polyps, endoscopists choose different endoscopic polypectomy techniques. With the rapid development of endoscopic resection techniques, cold polypectomy has gained broad attention. Cold polypectomy can effectively avoid electrocoagulation syndrome and reduce complications such as perforation and delayed bleeding caused by electrocoagulation injury.<sup>4,5</sup> It has the advantages of simple operation, less time-consuming and fewer complications. In 2017, the European Society of Gastrointestinal Endoscopy (ESGE) Clinical Guideline recommended cold snare polypectomy (CSP) for the resection of small polyps sized  $\leq 5$  mm and sessile polyps sized 6–9 mm.<sup>6</sup> Cold snare endoscopic mucosal resection (CS-EMR) combined CSP with submucosal injection allows for higher complete resection rate and safety. A randomised controlled trial (RCT) showed that the complete resection rate of sessile polyps sized 6–10 mm by CS-EMR was higher than 90%, which was

non-inferior to hot snare endoscopic mucosal resection (HS-EMR).<sup>7</sup> CS-EMR has also been used to resect larger polyps sized  $\geq 10$  mm in some observational studies.<sup>8-10</sup>

For sessile polyps larger than 10 mm, there is no definitive conclusion on the optimal endoscopic resection technique, and the use of cold resection remains debatable. 2017 ESGE guidelines suggested hot snare polypectomy (HSP)/HS-EMR as the standard treatment for this type of polyps.<sup>6</sup> In 2020, CSP and HSP (with or without submucosal injection) were both suggested for sessile polyps sized 10–19 mm by Endoscopic Removal of Colorectal Lesions—Recommendations by the US Multi-Society Task Force on Colorectal Cancer.<sup>11</sup> However, the evidence for these recommendations was rated low quality, and relevant references were all observational studies. We design a single-centre RCT to compare the efficacy and safety of CS-EMR and HS-EMR for the resection of non-pedunculated colorectal polyps sized 10–19 mm, laying down evidence for endoscopic resection techniques for large non-pedunculated polyps.

## METHODS

### Study design

This study is a single-centre, randomised, non-inferiority trial that enrolls patients who undergo colonoscopy in the Digestive Endoscopy Center of Peking Union Medical College Hospital (PUMCH). Eligible polyps found during colonoscopy examination will be randomly assigned to the CS-EMR group and the HS-EMR group at a 1:1 ratio. Figure 1 shows a flow chart of the study design. The schematic diagram recommended by Standard Protocol Items: Recommendations for Interventional Trials is presented in table 1.<sup>12</sup>

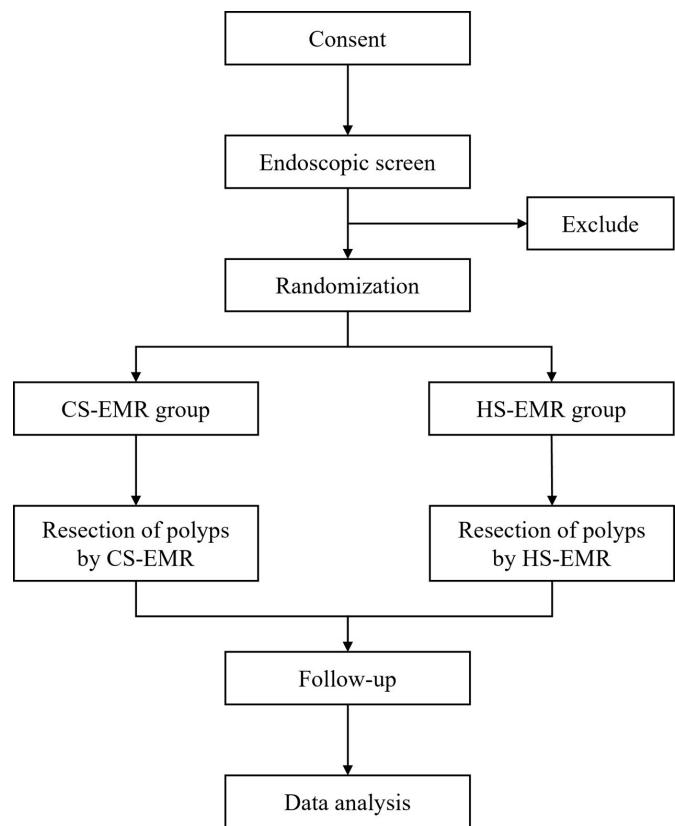
### Study sites and recruitment procedures

This clinical trial is conducted in PUMCH in Beijing, China. Patients undergoing colonoscopy in the Digestive Endoscopy Center of PUMCH will be recruited in the study. For patients who agree to participate in the study and sign an informed consent (online supplemental file 1), physicians will screen them based on clinical data and endoscopic findings to assess whether they meet the inclusion criteria.

### Inclusion/exclusion criteria

Eligible patients meet the following inclusion criteria: (1) 18–80 years of age; (2) undergo colonoscopy in the Digestive Endoscopy Center of PUMCH; (3) volunteer to participate in this study and sign informed consent; (4) at least one polyp sized 10–19 mm (Paris classification Ia or IIa) revealed by endoscopic examination.

The exclusion criteria are as follows: (1) American Society of Anesthesiologists status class 3 or above; (2) poor bowel preparation (Boston Bowel Preparation Scale  $< 6$  points); (3) endoscopic features indicating submucosal infiltration or malignancy; (4) oral anticoagulants, or antiplatelet agents, or known blood coagulation



**Figure 1** Flow chart showing the trial design. CS-EMR, cold snare endoscopic mucosal resection; HS-EMR, hot snare endoscopic mucosal resection.

disorders, or bleeding tendency (platelets  $< 50 \times 10^9/L$  or international normalized ratio  $> 1.5$ ); (5) a history of colorectal resection; (6) emergent colonoscopy (haemodynamic instability and/or continued active gastrointestinal bleeding and/or requiring intensive care patients); (7) inflammatory bowel disease, familial polyposis and colorectal cancer; (8) pregnancy or lactation; (9) severe cardiopulmonary dysfunction, cirrhosis, chronic kidney disease, other malignant tumours or severe infectious diseases.

### Randomisation and concealment

Eligible polyps will be randomly assigned (1:1) to the CS-EMR group and the HS-EMR group. Randomisation is stratified by polyp size (10–14 mm or 15–19 mm) using random block sizes of 4, 6 and 8. A computer-generated ('blockrand' package in R, <https://CRAN.R-project.org/package=blockrand>) randomisation sequence is prepared by an investigator who has no clinical involvement in the treatment procedure and concealed by placing the assignments in opaque, sequentially numbered envelopes. When an eligible polyp is identified during colonoscopy, an assistant will open the envelope to reveal the assigned polypectomy technique. If more than one eligible polyp is found in a patient, randomisation will be conducted for each polyp. There is no upper limit to the number of eligible polyps in each patient. This study was not blinded.

**Table 1** Schedule of enrolment, interventions and assessments

Content	Study period					
	Enrolment	Preallocation	Allocation	Postallocation		
	Screening and baseline assessment	Bowel preparation and endoscopic screening	Randomisation and polypectomy	Pathological examination	Follow-up	Close-out
Timepoint	T <sub>0</sub>	T <sub>1</sub> 0 day	T <sub>2</sub> 0 day	T <sub>3</sub> 0–14 days	T <sub>4</sub> 14 days	T <sub>5</sub> 14 days
Enrolment						
Eligible screen	×					
Informed consent	×					
Bowel preparation		×				
Endoscopic screening		×				
Allocation			×			
Interventions						
CS-EMR			×			
HS-EMR			×			
Assessment						
Baseline data	×					
BBPS score		×				
Polyp assessment		×				
Polypectomy procedure			×			
Pathological assessment				×	×	×
Safety assessment			×	×	×	×

BBPS, Boston Bowel Preparation Scale; CS-EMR, cold snare endoscopic mucosal resection; HS-EMR, hot snare endoscopic mucosal resection.

## Procedures

All endoscopic procedures will be performed by experienced endoscopists (conducting more than 1000 polypectomy cases and skilled in EMR) using the same colonoscope (CF290; Olympus Medical Systems Corporation, Tokyo, Japan). All patients will undergo standard split-dose bowel preparation by drinking laxatives before endoscopy. All endoscopic procedures will be conducted under local or general anaesthesia. The size of the polyp will be estimated by visual comparison with the opening snare (diameter 2.5 cm; AS-1-S; Wilson-Cook Medical Incorporated; Winston-Salem, USA). Polyps are measured in increments of 1 mm.

For both CS-EMR and HS-EMR groups, white light imaging (WLI) and narrow-band imaging (NBI) will be used to observe polyps and determine the boundary. To lift the lesion, methylene blue-tinted 1:10 000 epinephrine saline will be injected into the submucosal space around the lesion with an injection needle (NM-400U-0423; Olympus Medical Systems Corporation). In the CS-EMR group, the polyp and 1–2 mm of surrounding mucosa will be snared and transected mechanically. In the HS-EMR group, the snare will be placed around the lesion, and then cautery will be applied using the electrosurgical generator (VIO300D; ERBE Elektromedizin GmbH, Tübingen, Germany), set to ENDO CUT Q mode with effect 3 (duration 2, interval 4) and FORCED COAG

mode with effect 2 (limit 50 W). The electrosurgical generator will also be used if polyps cannot be resected in the CS-EMR group. The change of randomly assigned technique will be recorded in detail.

After removal of the polyp, the resection site will be rinsed and observed to determine if residual lesions are present using WLI and NBI. Specimens will be retrieved, flattened and fixed by formalin for pathology examination. When the en-bloc resection is not achieved, piecemeal specimens were first reconstituted by the endoscopist as completely as possible. If the reconstitution is failed, five biopsy samples (four biopsies obtained in a four-quadrant fashion from the polypectomy site margins; one biopsy from the base) will be taken for pathological evaluation. If no adverse events, such as active bleeding and perforation, or other risk factors for predicting adverse events are observed, no clips will be used to close the mucosa defect.

All patients will return for a follow-up visit at the outpatient department or be followed up by telephone contact 14 days after the polypectomy to obtain pathological results and assess for delayed adverse events.

## Outcome measurement

The primary outcome is the complete resection assessed by pathological examination. The resection is considered histologically complete if the lateral margins of the

resected polyps are surrounded by normal tissue, and the vertical margin is free of neoplasia tissue. If en-bloc resection is not achieved, five biopsies are applied to evaluate the histological completeness of resection.

Secondary outcomes include en-bloc resection, the occurrence of adverse events, the number of endoscopic clips used for each resected polyp, resection time and costs related to endoscopic resection. Adverse events include intraprocedural bleeding (any immediate episode requiring any form of endoscopic haemostasis or oozing for more than 60 s), intraprocedural perforation (endoscopic observation of perforation requiring sealing with clips), delayed bleeding (any episode requiring emergency department presentation, hospitalisation or reintervention within 14 days), delayed perforation (any perforation within 14 days) and post-polypectomy electrocoagulation syndrome (abdominal pain, fever, leucocytosis, raised C reactive protein or peritoneal irritation symptoms/signs that occurred after colonoscopic polypectomy with electrocoagulation, without proven perforation).<sup>13</sup> Resection time is recorded from the first occurrence of the injection needle under the endoscope visual field to the complete removal of the polyp. Total cost includes both treatment cost and material cost for the polyp resection.

### Sample size calculation

According to a previous study, the complete resection rate of 10–19 mm sessile polyps by EMR was 92.2%.<sup>14</sup> We hypothesise that HS-EMR of 10–19 mm colorectal polyps will yield a complete resection rate of at least 92%. We assume that CS-EMR will not be inferior with a non-inferiority margin of -10%. With a one-sided  $\alpha$  value of 0.025 and a power of 80%, the estimated sample size is 232 polyps (116 per group).

### Data management

Data collection will be performed using a standardised case report form during the outpatient appointment, the procedure of colonoscopy and the follow-up. The data can be verifiable from the medical record. All researchers and clinicians have mastered the details of this study. All participant-identifiable data will be separately and securely stored at the study site. Researchers will permit trial-related monitoring, audits and regulatory inspections, providing direct access to source data and documents. The results of this trial will be published in an open-access way.

### Statistical analyses

Intention-to-treat analysis and per-protocol analysis will be performed and reported. For the primary outcome, sequential tests are designed to control for a type I error  $\alpha$  of 0.025 (one-sided). First, the non-inferiority test will be conducted between the CS-EMR group and the HS-EMR group, and the two-sided 95% CI of risk difference (RD) between the two groups will be calculated. If the lower limit of the two-sided 95% CI of RD was greater than

-10%, it was considered that CS-EMR was non-inferior to HS-EMR. If non-inferiority is shown, then the superiority test will be performed to calculate the two-sided 95% CI of RD between groups. If the lower limit of the two-sided 95% CI is greater than 0, it is considered that CS-EMR is superior to HS-EMR. If non-inferiority is not established, the superiority test will not be performed.

We will present simple descriptive statistics (means, SD, medians, IQRs for continuous variables and frequencies, and percentages for categorical variables). Categorical variables will be compared using the  $\chi^2$  test and Fisher exact test, and continuous variables will be compared using the t-test and Mann-Whitney U test. Relative risks or mean differences with 95% CI will be calculated. A two-sided p value less than 0.05 will be regarded as statistical significance in the analyses of secondary outcomes. Adjustments for multiple comparisons between secondary outcomes will not be conducted. We will perform subgroup analysis based on polyp characteristics (size, location, Paris classification, pathology). Data analysis will be conducted using IBM SPSS Statistics V.23 (IBM Corp).

### Patient and public involvement

Patients or the public were not involved in the trial design.

### Ethics and dissemination

The study has been approved by the institutional review board of the Peking Union Medical College Hospital (No. K2203). Registration data are shown in [table 2](#). Safety reporting will follow the plan, and all adverse events will be recorded and informed institutional review board. There is no independent data monitoring committee because this trial is single-centre, open-label and low-risk.

Any modifications to the protocol which may impact the conduct of the study and the potential benefit of the patient or may affect patient safety will require a formal amendment to the protocol. Such amendment will be communicated to all investigators, approved by the institutional review board and trial registries, and notified to local health authorities.

### DISCUSSION

The study aims to evaluate the efficacy and safety of CS-EMR, compared with HS-EMR, for non-pedunculated colorectal polyps sized 10–19 mm. For polyps with a diameter  $\geq 10$  mm, the incidence of carcinoma in situ or severe dysplasia is higher.<sup>15</sup> In addition, considering the large wound, high recurrence rate and failure to ensure complete resection, there is no clear conclusion on applying cold resection technology in large polyps. High-quality research evidence is also very limited.

Before designing this clinical trial, we conducted a comprehensive literature review. Pohl *et al* performed a large scale prospective study of 346 neoplastic polyps (the complete adenoma resection study). Incomplete resection rate was increased with polyp size and was significantly higher for large (10–20 mm) than small (5–9 mm)

**Table 2** Registration data

Data category	Information
Primary registry and trial identifying number	ClinicalTrials.gov NCT05545787
Date of registration	15 September 2022
Primary sponsor	QJ, Peking Union Medical College Hospital
Central contact person	QJ, MD flyerj@sina.com
Public title	Cold or Hot Snare Endoscopic Mucosal Resection for 10–19 mm Non-pedunculated Colorectal Polyps
Scientific title	A Prospective, Randomized, Non-inferiority Study to Compare Efficacy and Safety of Cold Snare Endoscopic Mucosal Resection and Hot Snare Endoscopic Mucosal Resection in Treatment for 10–19 mm Non-pedunculated Colorectal Polyps
Countries of recruitment	China
Health condition	Colorectal polyp
Intervention(s)	Experimental: CS-EMR Experimental: HS-EMR
Inclusion and exclusion criteria	Ages eligible for the study: 18–80 years; sexes eligible for the study: both; accepts healthy volunteers: no  Inclusion criteria: 18–80 years, undergo colonoscopy, informed consent, non-pedunculated polyp sized 10–19 mm  Exclusion criteria: ASA class 3 or above; poor bowel preparation, submucous infiltration or malignancy, oral anticoagulants or antiplatelet agents, blood coagulation disorders or bleeding tendency, a history of colorectal resection, emergency colonoscopy, IBD, FAP, CRC, pregnancy or lactation, other severe diseases
Study type	Interventional  Allocation: randomised; intervention model: parallel assignment; masking: none  Primary purpose: treatment
Target sample size	232
Recruitment status	Not yet recruitment
Primary outcome(s)	Complete resection rate
Key secondary outcomes	En-bloc resection rate, intraprocedural or delayed bleeding and perforation, etc

ASA, American Society of Anesthesiologists; CRC, colorectal cancer; CS-EMR, cold snare endoscopic mucosal resection; FAP, familial polyposis; HS-EMR, hot snare endoscopic mucosal resection; IBD, inflammatory bowel disease.

neoplastic polyps (17.3% vs 6.8%).<sup>16</sup> According to another prospective observational cohort study including 163 sessile serrated polyps  $\geq 10$  mm, only two lesions (1.2%) contained residual serrated tissue in marginal biopsy.<sup>9</sup> Yabuuchi *et al* recently reported that histological complete resection rate of CS-EMR for 10–14 mm colorectal polyps was 63.8% in a prospective single-arm observational trial.<sup>17</sup> In a meta-analysis of eight studies (522 polyps with an average diameter of 17.5 mm) that estimated the safety and efficacy of cold resection of large polyps by CSP and CS-EMR, the complete resection rate was 99.3%, the recurrence rate was 4.1% and the incidence of adverse events was 1.1%.<sup>18</sup>

Evidence from RCT is still limited. The results of an RCT from China showed that the complete removal rates of 6–20 mm polyps by CSP, CS-EMR and EMR were 81.6%, 94.1% and 95.5%, respectively. The complete resection rate of CS-EMR was similar to EMR and significantly higher than the CSP group, and the incidence of delayed complications was low.<sup>19</sup> Another RCT compared the efficacy of CSP, CS-EMR, HSP and

HS-EMR in removing sessile polyps sized 6–15 mm. There were no incomplete resections and serious adverse events in the CSP group, and the time of resection was shorter. In addition, all incomplete resections in this study occurred in the 10–15 mm polyp group, suggesting that further research on 10–19 mm polyps was of clinical significance.<sup>20</sup>

Therefore, based on clinical practice concerns and previous research results, we pay attention to CS-EMR technology for 10–19 mm lesions and design this non-inferiority RCT. We hope that the results of this trial will provide recommendations for the selection of endoscopic resection techniques.

#### Trial status

The protocol version number and date: V.4.1, 29 March 2023. The study was conceived and designed in 2022. Enrolment began in 2022 and is expected to end in December 2025. At the time of manuscript preparation, enrolment in this study has started.

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**Contributors** QJ and XY contributed equally to this work and are cofirst authors. QJ and XY are involved in the study concept and design and drafting of the manuscript. YZ contributes to improving the methodology of this trial. DWa, SZ, YF and AY participate in the study design. DWu is the corresponding author involved in the study concept and design and the revision of the manuscript. All authors read and approved the final manuscript.

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