



UMIN-CTR Clinical Trial

[BACK](#) [TOP](#) [🌐 UMIN-CTR English Home](#) [🌐 Glossary \(Simple\)](#) [🌐 FAQ](#) [🌐 Search clinical trials](#)

Name:		UMIN ID:	
Recruitment status		Completed	
Unique ID issued by UMIN		UMIN000015016	
Receipt No.		R000017467	
Official scientific title of the study		Removal of small colorectal polyps from 3 to 6mm in size: a prospective randomized comparative study between cold snare polypectomy and hot biopsy	
Date of disclosure of the study information		2014/10/01	
Last modified on		2016/06/15	

* This page includes information on clinical trials registered in UMIN clinical trial registred system.

* We don't aim to advertise certain products or treatments

Basic information	
Official scientific title of the study	Removal of small colorectal polyps from 3 to 6mm in size: a prospective randomized comparative study between cold snare polypectomy and hot biopsy
Title of the study (Brief title)	A prospective randomized comparative study between CSP and HOT
Region	Japan

Condition	
Condition	Patients who have colorectal polyps
Classification by specialty	Gastroenterology
Classification by malignancy	Others
Genomic information	NO

Objectives	
Narrative objectives1	To investigate the efficacy and safety of cold snare polypectomy and hot biopsy in the removal of small colorectal polyps from 3 to 6 mm in size
Basic objectives2	Safety,Efficacy

Basic objectives -Others	
Trial characteristics_1	Confirmatory
Trial characteristics_2	Pragmatic
Developmental phase	Not applicable

Assessment	
Primary outcomes	Curative resection rate Evaluation of cut margin 1)Endoscopic evaluation: to confirm a tumor-free cut margin with magnified endoscopic view 2)Pathological evaluation: to confirm a tumor-free cut margin with microscopic view En bloc resection rate
Key secondary outcomes	Polyp retrieval rate Immediate bleeding, immediate perforation after polypectomy Delayed bleeding, delayed perforation after polypectomy Clipping required forRequired for bleeding or perforation Local recurrence rate

In outcomes field, the entry of just a few words such as "safety" or "efficiency" will not be accepted. Specify the name of outcome measures, including the time when you plan to measure. Usually, only one primary outcome is accepted. Write the other outcomes in "secondary outcomes" field.

Base	
Study type	Interventional

Study design	
Basic design	Parallel
Randomization	Randomized
Randomization unit	Individual
Blinding	Single blind -participants are blinded
Control	Active
Stratification	YES

Dynamic allocation	YES
Institution consideration	Institution is considered as a block.
Blocking	YES
Concealment	Central registration

Intervention	
No. of arms	2
Purpose of intervention	Treatment
Type of intervention	Maneuver
Interventions/Control_1	cold snare polypectomy
Interventions/Control_2	hot snare polypectomy
Interventions/Control_3	
Interventions/Control_4	
Interventions/Control_5	
Interventions/Control_6	
Interventions/Control_7	
Interventions/Control_8	
Interventions/Control_9	
Interventions/Control_10	

In interventions field, include the details of interventions, such as duration, amount, and frequency. If the intervention includes prescription or use of medical devices, duration is required.

Eligibility	
Age-lower limit	20 years-old <=
Age-upper limit	Not applicable
Gender	Male and Female

Key inclusion criteria	more than 20 years old Patients undergoing removal of colorectal polyps of target size Written informed consent
Key exclusion criteria	Polyps suspected of being cancerous Patients with inflammatory bowel disease Hyperplastic polyps less than 5 mm in the distal colorectum Patient without informed consent Others who did not agree to cooperate with the study
Target sample size	300

Research contact person	
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Sponsor	
Institute	Department of Gastroenterology and Hepatology Kinki University, School of Medicine
Institute	
Institute	

Department	
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Sponsor means an organization that is responsible for plan, deployment and report of the research including funding management. It doesn't mean funding agency". Therefore, all clinical trial should have the one.

Funding Source	
Organization	none
Organization	
Division	
Category of Funding Organization	Self funding
Nationality of Funding Organization	

Other related organizations	
Co-sponsor	
Name of secondary fund er(s)	

Secondary IDs	
Secondary IDs	NO
Study ID_1	
Org. issuing International ID_1	
Study ID_2	
Org. issuing International ID_2	
IND to MHLW	

Institutions	
Institutions	

Other administrative information	
Date of disclosure of the study infor	2014 Year 10 Month 01 Day

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Progress	
Recruitment status	Completed
Date of protocol fixation	2014 Year 10 Month 01 Day
Anticipated trial start date	2014 Year 10 Month 01 Day
Last follow-up date	
Date of closure to data entry	
Date trial data considered complete	
Date analysis concluded	

Related information	
URL releasing protocol	
Publication of results	Unpublished
URL releasing results	
Results	
Other related information	

Management information	
Registered date	2014 Year 09 Month 01 Day
Last modified on	2016 Year 06 Month 15 Day

Link to view the page	
URL(English)	https://upload.umin.ac.jp/cgi-open-bin/ctr_e/ctr_view.cgi?recptno=R000017467

Back

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