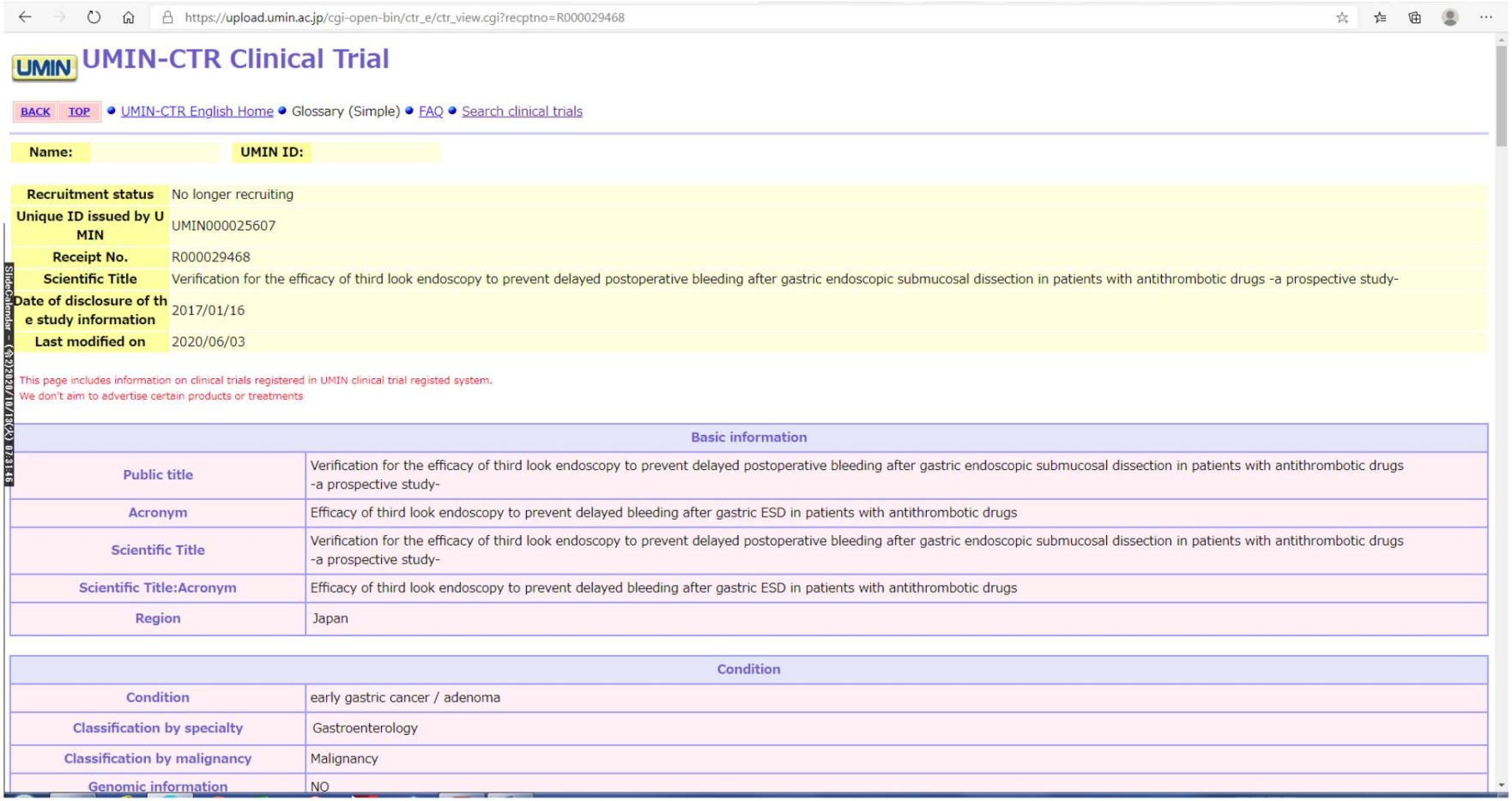
Clinical trial registration statement: The study was registered at UMIN Clinical Trials Registry System, using identifier 000025607. Details can be found at https://www.umin.ac.jp/ctr/.



https://upload.umin.ac.jp/cgi-open-bin/ctr_e/ctr_view.cgi?recptno=R000029468

UMIN-CTR Clinical Trial

BACK TOP • UMIN-CTR English Home • Glossary (Simple) • FAQ • Search clinical trials

Name:		UMIN ID:	

Recruitment status	No longer recruiting
Unique ID issued by UMIN	UMIN000025607
Receipt No.	R000029468
Scientific Title	Verification for the efficacy of third look endoscopy to prevent delayed postoperative bleeding after gastric endoscopic submucosal dissection in patients with antithrombotic drugs -a prospective study-
Date of disclosure of the study information	2017/01/16
Last modified on	2020/06/03

This page includes information on clinical trials registered in UMIN clinical trial registed system.
We don't aim to advertise certain products or treatments

Basic information	
Public title	Verification for the efficacy of third look endoscopy to prevent delayed postoperative bleeding after gastric endoscopic submucosal dissection in patients with antithrombotic drugs -a prospective study-
Acronym	Efficacy of third look endoscopy to prevent delayed bleeding after gastric ESD in patients with antithrombotic drugs
Scientific Title	Verification for the efficacy of third look endoscopy to prevent delayed postoperative bleeding after gastric endoscopic submucosal dissection in patients with antithrombotic drugs -a prospective study-
Scientific Title:Acronym	Efficacy of third look endoscopy to prevent delayed bleeding after gastric ESD in patients with antithrombotic drugs
Region	Japan

Condition	
Condition	early gastric cancer / adenoma
Classification by specialty	Gastroenterology
Classification by malignancy	Malignancy
Genomic information	NO

Objectives	
Narrative objectives1	To verify the efficacy of third look endoscopy to prevent delayed postoperative bleeding after gastric endoscopic submucosal dissection in patients with antithrombotic drugs
Basic objectives2	Safety,Efficacy
Basic objectives -Others	
Trial characteristics_1	Confirmatory
Trial characteristics_2	Pragmatic
Developmental phase	Phase II

Assessment	
Primary outcomes	Overall delayed bleeding rate
Key secondary outcomes	the early phase delayed bleeding rate the late phase delayed bleeding rate the delayed bleeding rate compared with the historical control group using propensity score matching.

Base	
Study type	Interventional

Study design	
Basic design	Single arm
Randomization	Non-randomized
Randomization unit	
Blinding	Open -no one is blinded
Control	Historical
Stratification	NO
Dynamic allocation	NO
Institution consideration	Institution is not considered as adjustment factor.
Blocking	NO
Concealment	No need to know

Intervention	
No. of arms	1
Purpose of intervention	Treatment
Type of intervention	Maneuver
Interventions/Control_1	To perform 3rd-look endoscopy 5days later after ESD
Interventions/Control_2	
Interventions/Control_3	
Interventions/Control_4	
Interventions/Control_5	
Interventions/Control_6	
Interventions/Control_7	
Interventions/Control_8	
Interventions/Control_9	
Interventions/Control_10	

Eligibility	
Age-lower limit	20 years-old <=
Age-upper limit	Not applicable
Gender	Male and Female
Key inclusion criteria	(1)patients with histological diagnosis as gastric adenocarcinoma or adenoma (2)patients without history of gastrectomy or esophagectomy (3)patients with antithrombotic agents regardless of drug withdrawal (4)PS(ECOG)0,1,2 (5) patients who can be followed up more than 28days after ESD (6)patients with written informed consent of this study
Key exclusion criteria	(1) Patient with severe infection (2) Patient who are pregnant, may be pregnant, or prefer pregnancy during treatment (3)for Mental disease, dementia,it is difficult to participate study (4) Patient with unstable angina, or myocardial infarction within 6 months. (5)Patient with respiratory diseases requiring continuous oxygen therapy

Key exclusion criteria	(2) Patient who are pregnant, may be pregnant, or prefer pregnancy during treatment (3)for Mental disease, dementia,it is difficult to participate study (4) Patient with unstable angina, or myocardial infarction within 6 months. (5)Patient with respiratory diseases requiring continuous oxygen therapy (6)Patient with uncontrollable hypertension (7)Patient with uncontrollable Diabetes (8)anemia requiring transfusion(Hb<7.0g/dl), Easy to bleed for low platelet (Plt<50000) (9) Patient judged inappropriate
Target sample size	100

Research contact person		
Name of lead principal investigator	1st name	Kingo
	Middle name	
	Last name	hirasawa
Organization	Yokohama City University Medical Center	
Division name	Division of Endoscopy	
Zip code	232-0024	
Address	4-57, urahunecho, minami ward, Yokohama city, Kanagawa Prefecture	
TEL	0452615656	
Email	ryosuke@yokohama-cu.ac.jp	

Public contact		
Name of contact person	1st name	Kingo
	Middle name	
	Last name	hirasawa
Organization	Yokohama City University Medical Center	
Division name	Division of Endoscopy	
Zip code	232-0024	
Address	4-57, urahunecho, minami ward, Yokohama city, Kanagawa Prefecture	
TEL	0452615656	
Homepage URL		

Homepage URL	
Email	ryosuke@yokohama-cu.ac.jp

Sponsor	
Institute	Yokohama City University Medical Center
Institute	
Department	

Funding Source	
Organization	Yokohama City University Medical Center
Organization	
Division	
Category of Funding Organization	Self funding
Nationality of Funding Organization	Japan

Other related organizations	
Co-sponsor	None
Name of secondary funder(s)	

IRB Contact (For public release)	
Organization	institutional review board of Yokohama City University
Address	3-9, fukuura, kanazawa ward, Yokohama city, Kanagawa Prefecture
Tel	045-370-7627
Email	rinri@yokohama-cu.ac.jp

Secondary IDs	
Secondary IDs	NO
Study ID_1	
Org. issuing International ID_1	

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	横浜市立大学附属市民総合医療センター Yokohama City University Medical Center

Other administrative information	
Date of disclosure of the study information	2017 Year 01 Month 16 Day

Related information	
URL releasing protocol	
Publication of results	Unpublished

Result	
URL related to results and publications	
Number of participants that the trial has enrolled	100
Results	
Results date posted	
Results Delayed	
Results Delay Reason	
Date of the first journal publication of resu	

Date of the first journal publication of results	
Baseline Characteristics	
Participant flow	
Adverse events	
Outcome measures	
Plan to share IPD	
IPD sharing Plan description	

Progress	
Recruitment status	No longer recruiting
Date of protocol fixation	2017 Year 01 Month 16 Day
Date of IRB	2016 Year 12 Month 22 Day
Anticipated trial start date	2017 Year 01 Month 16 Day
Last follow-up date	2020 Year 03 Month 31 Day
Date of closure to data entry	2020 Year 03 Month 31 Day
Date trial data considered complete	2020 Year 03 Month 31 Day
Date analysis concluded	2021 Year 03 Month 31 Day

Other	
Other related information	

Management information	
Registered date	2017 Year 01 Month 10 Day
Last modified on	2020 Year 06 Month 03 Day

Date of closure to data entry	2020 Year 03 Month 31 Day
Date trial data considered complete	2020 Year 03 Month 31 Day
Date analysis concluded	2021 Year 03 Month 31 Day

Other	
Other related information	

Management information	
Registered date	2017 Year 01 Month 10 Day
Last modified on	2020 Year 06 Month 03 Day

Link to view the page	
URL(English)	https://upload.umin.ac.jp/cgi-open-bin/ctr_e/ctr_view.cgi?recptno=R000029468

Research Plan	
Registered date	File name

Research case data specifications	
Registered date	File name

Research case data	
Registered date	File name

Back