

 UMIN-CTR Clinical Trial

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Recruitment status	: Completed
Unique trial Number	: UMIN000012097
Title of the study	: A prospective randomized study to compare the tolerability of the magnifying narrow-band imaging endoscopy with lugol chromoendoscopy for esophageal cancer screening
Date of formal registration (=Date of ICMJE and WHO compliant trial information registration and disclosure)	: 2013/10/22
Date and time of last update	: 2014/04/22 15:19:36

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Basic information	
Item	Value
Official scientific title of the study	A prospective randomized study to compare the tolerability of the magnifying narrow-band imaging endoscopy with lugol chromoendoscopy for esophageal cancer screening
Title of the study (Brief title)	A prospective randomized study to compare the tolerability of the magnifying narrow-band imaging endoscopy with lugol chromoendoscopy for esophageal cancer screening
Region	Japan

Condition	
Item	Value
Condition	esophageal cancer
Classification by specialty	Gastroenterology
Classification by malignancy	Malignancy
Genomic information	NO

Objectives	
Item	Value
Narrative objectives1	To compare the adverse symptoms of the magnifying narrow-band imaging endoscopy with lugol chromoendoscopy for esophageal cancer screening
Basic objectives2	Efficacy
Basic objectives -Others	
Trial characteristics_1	Confirmatory
Trial characteristics_2	Pragmatic
Developmental phase	Not applicable

Assessment	
Item	Value
Primary outcomes	Visual analogue scale for heartburn after the examination
Key secondary outcomes	Visual analogue scale for retrosternal pain or dyspnea after the examination

Base	
Item	Value
Study type	Interventional

Study design	
Item	Value
Basic design	Parallel
Randomization	Randomized
Randomization unit	Individual
Blinding	Open -no one is blinded
Control	Active
Stratification	YES
Dynamic allocation	NO
Institution consideration	
Blocking	
Concealment	

Intervention	
Item	Value
No. of arms	2
Purpose of intervention	Prevention
Type of intervention	Device,equipment
Interventions/Control_1	magnifying narrow-band imaging endoscopy
Interventions/Control_2	lugol chromoendoscopy
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	
Item	Value
Age-lower limit	Not applicable
Age-upper limit	Not applicable
Gender	Male and Female
Key inclusion criteria	Patients who have more than six points in health risk appraisal-flushing score for esophageal cancer or patients who have history of head and neck squamous cell carcinoma
Key exclusion criteria	1)patients with iodine allergy 2)patients with severe organ failure 3)patients who have been judged as inappropriate for this study
Target sample size	52

Research contact person	
Item	Value
Name of lead principal investigator	Ryuta Takenaka
Organization	Tsuyama central hospital
Division name	Department of Gastroenterology
Address	1756, Kawasaki, Tsuyama, Okayama, Japan
TEL	+81-868-21-8111
Email	rtakenak@gmail.com

Public contact	
Item	Value
Name of contact person	Yasushi Yamasaki
Organization	Tsuyama central hospital
Division name	Department of Gastroenterology
Address	1756, Kawasaki, Tsuyama, Okayama, Japan
TEL	+81-868-21-8111
Homepage URL	
Email	yasshifive@yahoo.co.jp

Sponsor	
Item	Value
Name of primary sponsor	Tsuyama central hospital

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	
Item	Value
Source of funding	Tsuyama central hospital
Category of Org.	Self funding
Nation of funding	

Other related organizations	
Item	Value
Co-sponsor	
Name of secondary funder(s)	

Secondary study IDs	
Item	Value
Secondary study IDs	NO
Secondary study ID_1	
Org. issuing Secondary study ID_1	

Secondary study ID_2	
Org. issuing Secondary study ID_2	
IND to MHLW	

Institutions	
Item	Value
Institutions	津山中央病院(岡山県)

Progress	
Item	Value
Recruitment status	Completed
Date of protocol fixation	2012/02/03
Anticipated trial start date	2012/03/21
Last follow-up date	2015/03/21
Date of closure to data entry	2015/03/21
Date trial data considered complete	2015/03/21
Date analysis concluded	2015/03/21

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

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Date of registration	2013/10/22
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Link to view	
URL(Japanese)	https://upload.umin.ac.jp/cgi-open-bin/ctr/ctr.cgi?function=brows&action=brows&recptno=R000014135&type=summary&language=J
URL(English)	https://upload.umin.ac.jp/cgi-open-bin/ctr/ctr.cgi?function=brows&action=brows&recptno=R000014135&type=summary&language=E

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