

<b>Recruitment status</b>	: <b>Completed</b>
Unique trial Number	: UMIN000008492
Title of the study	: Multicenter study for Endoscopic Pre-Operative Biliary Drainage in Patients with Malignant Distal Biliary Obstruction
Date of formal registration (=Date of ICMJE and WHO compliant trial information registration and disclosure)	: 2012/07/22
Date and time of last update	: 2013/09/16 10:17:38

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Basic information	
Item	Value
Official scientific title of the study	Multicenter study for Endoscopic Pre-Operative Biliary Drainage in Patients with Malignant Distal Biliary Obstruction
Title of the study (Brief title)	Multicenter E-POD study
Region	Japan

Condition	
Item	Value
Condition	Pancreas head ca, extrahepatic bile duct ca
Classification by specialty	Hepato-biliary-pancreatic medicine Hepato-biliary-pancreatic surgery
Classification by malignancy	Malignancy
Genomic information	NO

Objectives	
Item	Value
Narrative objectives1	To evaluate the efficacy of endoscopic preoperative biliary drainage.
Basic objectives2	Safety,Efficacy
Basic objectives -Others	
Trial characteristics_1	
Trial characteristics_2	
Developmental phase	

Assessment	
Item	Value
Primary outcomes	Additional endoscopic biliary drainage

Key secondary outcomes

Base	
Item	Value
Study type	Observational

Study design	
Item	Value
Basic design	
Randomization	
Randomization unit	
Blinding	
Control	
Stratification	
Dynamic allocation	
Institution consideration	
Blocking	
Concealment	

Intervention	
Item	Value
No. of arms	
Purpose of intervention	
Type of intervention	
Interventions/Control_1	
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	

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	
Item	Value
Age-lower limit	18 years-old <=
Age-upper limit	100 years-old >

Gender	Male and Female
Key inclusion criteria	Cases with pancreatic head cancer or extrahepatic bile duct cancer accompanied with obstructive jaundice and underwent endoscopic biliary drainage followed by resection
Key exclusion criteria	endoscopic biliary drainage in other hospital
Target sample size	300

Research contact person	
Item	Value
Name of lead principal investigator	Naoki Sasahira
Organization	Sempo Tokyo Takanawa Hospital
Division name	Gastroenterology
Address	3-10-11, Takanawa, Minato-Ku
TEL	+81-3-3443-9191
Email	sasahira-tyk@umin.ac.jp

Public contact	
Item	Value
Name of contact person	Naoki Sasahira
Organization	E-POD study group
Division name	E-POD study group
Address	3-10-11, Takanawa, Minato-Ku
TEL	+81-3-3443-9191
Homepage URL	
Email	sasahira-tyk@umin.ac.jp

Sponsor	
Item	Value
Name of primary sponsor	E-POD study group

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	No
Category of Org.	Self funding
Nation of funding	

Other related organizations	
Item	Value
Co-sponsor	

Name of secondary funder(s)	
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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	

Progress	
Item	Value
Recruitment status	Completed
Date of protocol fixation	2012/07/01
Anticipated trial start date	2012/07/10
Last follow-up date	2013/03/31
Date of closure to data entry	2013/05/31
Date trial data considered complete	2013/08/31
Date analysis concluded	2013/10/31

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

Item	Value
Date of registration	2012/07/22
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Link to view	
URL(Japanese)	<a href="https://upload.umin.ac.jp/cgi-open-bin/ctr/ctr.cgi?">https://upload.umin.ac.jp/cgi-open-bin/ctr/ctr.cgi?</a>

	function=brows&action=brows&recptno=R000009982&type=summary&language=J
URL(English)	https://upload.umin.ac.jp/cgi-open-bin/ctr/ctr.cgi? function=brows&action=brows&recptno=R000009982&type=summary&language=E

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