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Recruitment status

: **Completed**

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-tyky@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-tyky@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) | |
|-----------------------------|--|

| 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 |
| Date of last update | 2013/09/16 10:17:38 |

| Link to view | |
|---------------|---|
| URL(Japanese) | https://upload.umin.ac.jp/cgi-open-bin/ctr/ctr.cgi? |

| | |
|--------------|---|
| | 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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