Drainage
front page

Please return within one month after registration to: Antoni van Leeuwenhoek datacenter, Post Box 90203, 1006 BE Amsterdam

Patient study number ⌊_____⌋

Patient verification code *(mmyyyy of birth date patient)* ⌊_____⌋

Institute ⌊_____⌋

Physician's name ⌊_____⌋

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ANTONI VAN LEEUWENHOEK
NEDERLANDS KANKER INSTITUUT

Drainage

Randomization

Protocol version: 3.0 Feb 2014
CRF version: 2.0 Jun 2014

Institute _____ Patient number ____ Patient verification code ____

Please return within one month after registration to: Antoni van Leeuwenhoek datacenter, Post Box 90203, 1006 BE Amsterdam

Institute _____

Investigator _____

Name caller _____

Patient's birth date *(dd/mm/yyyy)* ____

Gender *(1= male, 2= female)* ☐

Date informed consent signature *(dd/mm/yyyy)* ____

INCLUSION CRITERIA	**YES**	**NO**
Diagnosis or suspicion of pHCCA	☐	■
No apparent signs of irresectability on CT scan and/or MRI, and scheduled to undergo a "curative" liver resection (may need additional lymph node biopsies or a diagnostic laparoscopy to further determine resectability)	☐	■
Inadequate pre-operative biliary drainage defined as: o For drainage naïve patients Serum Total Bilirubin (TB) level ≥ 50 µmol/L; o For drainage non-naïve patients Persistent hyperbilirubinemia or inadequate drainage of the FRL (future remnant liver)	☐	■
Signed informed consent	☐	■

EXCLUSION CRITERIA	**YES**	**NO**
Incomplete recovery from side-effects of any prior stenting attempt	■	☐
Signs of active cholangitis, defined as leukocytes ≥ $10*10^9$/L or antibiotic treatment for a suspicion of cholangitis within the past 5 days	■	☐

Drainage

Randomization

Institute _____ Patient number ____ Patient verification code ____

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	YES	**NO**
WHO performance score ≥ 3	☐	☐
Any contraindication for major surgery	☐	☐

	YES	**NO**
Is patient eligible?	☐	☐

Date of registration *(dd/mm/yyyy)* ____

Assigned patient study number ____

STRATIFICATION FACTORS

Tumor progression into the bilateral segmental bile ducts ☐
1= BC type I, II or III or intrahepatic CCA with involvement of the hepatic duct confluence
2= BC type IV or intrahepatic CCA with bilateral involvement of segmental bile ducts

Drainage naivety ☐
1= drainage naïve
2= prior drainage

Centrum of inclusion ☐
1= AMC
2= Erasmus MC
3= MUMC
4= UMCG

Date of treatment allocation *(dd/mm/yyyy)* ____

Treatment arm ☐
1= EBD
2= PTBD

Drainage

Baseline

Protocol version: 3.0 Feb 2014
CRF version: 2.0 Jun 2014

Institute _____ Patient number ____ Patient verification code ____

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Date of baseline visit *(dd/mm/yyyy)* ____

Date informed consent signature *(dd/mm/yyyy)* ____

Assigned treatment arm *(1= EBD, 2= PTBD)* ____

DEMOGRAPHY

Patient's birth date *(dd/mm/yyyy)* ____

Gender *(1= male, 2= female)* ____

SIGNIFICANT MEDICAL HISTORY

Is the patient suffering from, or has he/she ever suffered from significant medical conditions *(0= no, 1= yes)* ____
(if yes, please record details below)

Diagnosis	Year of first diagnosis	Status *(1= past, 2= latent, 3= active)*
1.....	____	____
2. …	____	____
3.....	____	____
4.....	____	____

PREVIOUS THERAPY

Prior surgery

Did the patient undergo prior liver, pancreas or biliary/galbladder surgery? *(0=no, 1=yes)* ____
(if yes, please record details below)

	Date procedure *(mm/yyyy)*
1.	____
2.	____
3. ..... ……	____

Institute _____ Patient number _____ Patient verification code _____

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Prior drainage procedures (at local hospital)

Did the patient undergo drainage procedures before randomization? *(0= no, 1= yes)* ☐

If yes, please specify

Number of drainage procedures *(1-4)* ☐

Type of drainage *(1= ERCP, 2= PTC, 3= both)* ☐

If ERCP, sphincterotomy performed *(0= no, 1= yes)* ☐

Success of stent insertion through stenosis *(0= no, 1= yes)* ☐

Were there procedure related complications *(0= no, 1= yes)* ☐

If yes, specify ☐

1= cholangitis
2= acute cholecystitis
3= acute pancreatitis
4= stent occlusion/dislocation
5= hemorrhage
6= perforation
7= portal vein thrombosis
8= other, specify……..

Sample date initial blood chemistry (i.e. prior to drainage at local hospital) *(dd/mm/yyyy)* ☐☐/☐☐/☐☐☐☐

Total Bilirubin *(µmol/l)* ☐☐☐

CLINICAL ASSESSMENT

Date assessment *(dd/mm/yyyy)* ☐☐/☐☐/☐☐☐☐

Height *(cm)* ☐☐☐

Weight *(kg)* ☐☐☐.☐

Approximate weight one year ago *(kg)* ☐☐☐.☐

WHO Performance status *(0- 4)* ☐

BRUSH

Was brush performed *(0= no, 1= yes)* ☐

If yes, date performed *(dd/mm/yyyy)* ☐☐/☐☐/☐☐☐☐

Result brush *(1= not malignant, 2= malignant)* ☐

Drainage

Baseline

Institute | Patient number | Patient verification code

Please return within one month after registration to: Antoni van Leeuwenhoek datacenter, Post Box 90203, 1006 BE Amsterdam

PREOPERATIVE DIAGNOSTICS

Echo + Doppler performed *(0= no, 1= yes)*

If yes, date performed *(dd/mm/yyyy)*

Multiphasic CT scan *(0= no, 1= yes)*

If yes, date performed *(dd/mm/yyyy)*

MRI/MRCP performed *(0= no, 1= yes)*

If yes, date performed *(dd/mm/yyyy)*

LIVER PARENCHYMA

Cirrhosis *(0= no, 1= yes)*

Atrophy *(0= no, 1= left, 2= right)*

TUMOR CHARACTERISTICS

Bismuth – Corlette classification *(1= I, 2= II, 3= IIIA, 4=IIIB, 5= IV, 6= intrahepatic right, 7= intrahepatic left)*

Tumor size on CT/MRI (RECIST 1.1) *(mm)*

Growth pattern on CT/MRI *(1-3)*
1= mass forming
2= intraductal
3= periductal

SURGICAL PLANNING

Future remnant liver as specified by MDT meeting

Left liver segments *(0= no, 1= yes)*

Right ventral segments *(0= no, 1= yes)*

Right dorsal segments *(0= no, 1= yes)*

DIAGNOSTIC LAPAROSCOPY *(0= no, 1= yes)*

If yes, date admittance *(dd/mm/yyyy)*

Date of operation *(dd/mm/yyyy)*

Date of discharge *(dd/mm/yyyy)*

Result of diagnostic laparoscopy *(1= resectable, 2= irresectable)*

ANTONI VAN LEEUWENHOEK
NEDERLANDS KANKER INSTITUUT

Drainage
Baseline

Protocol version: 3.0 Feb 2014
CRF version: 2.0 Jun 2014

Institute _____ Patient number ____ Patient verification code ____

Please return within one month after registration to: Antoni van Leeuwenhoek datacenter, Post Box 90203, 1006 BE Amsterdam

HEMATOLOGY

	Sample date *(dd/mm/yyyy)*	Value *(enter ND if not done)*	*(specify if other than standard unit)*	Sample date *(dd/mm/yyyy)*	Value *(enter ND if not done)*	*(specify if other than standard unit)*
CRP *(mg/l)*		___ . ___	……		___ . ___	……
Hemoglobin *(mmol/l)*		___ . ___	……		___ . ___	……
WBC count *(10^9/l)*		___ . ___	……		___ . ___	……
ANC *(10^9/l)*		___ . ___	……		___ . ___	……
APTT *(sec)*		___ . ___	……		___ . ___	……
PT-INR *(sec)*		___ . ___	……		___ . ___	……

CHEMISTRY

	Sample date *(dd/mm/yyyy)*	Value *(enter ND if not done)*	*(specify if other than standard unit)*	Sample date *(dd/mm/yyyy)*	Value *(enter ND if not done)*	*(specify if other than standard unit)*
Total Bilirubin* *(µmol/l)*		___ . ___	……		___ . ___	……
Direct Bilirubin *(µmol/l)*		___ . ___	……		___ . ___	……
Alk. phosphatase *(U/l)*		___ . ___	……		___ . ___	……
Y-GT *(U/l)*		___ . ___	……		___ . ___	……
Creatinine *(µmol/l)*		___ . ___	……		___ . ___	……
Albumin *(g/l)*		___ . ___	……		___ . ___	……
Amylase *(U/l)*		___ . ___	……		___ . ___	……

*(*must be value at randomization: this value is the reference value for evaluation of therapeutic success)*

Drainage

index drainage procedure = iEBD

Institute _____ Patient number ____ Patient verification code ____

Please return within one month after index drainage to: Antoni van Leeuwenhoek datacenter, Post Box 90203, 1006 BE Amsterdam

Date of iEBD procedure *(dd/mm/yyyy)* ____

PROCEDURE CHARACTERISTICS

Standard antibiotics prophylaxis *(0= no, 1= yes)* ☐

Antibiotics given ☐
1= 2000 mg ceftriaxone + 5 mg/kg gentamycin
2= 2000 mg ceftriaxone alone
3= 1200 mg Augmentin
8= other, specify……

Standard post-ERCP NSAID suppository *(100 mg Diclofenac)* *(0= no, 1= yes)* ☐

Sphincterotomy *(0= no, 1= yes, 2= sphincterotomy performed before study)* ☐

Stent placement through stenosis successful *(0= no, 1= yes)* ☐

If no, reason ☐
1= procedure discontinued before stent placement.
2= unable to cannulate obstruction.
8= other, specify……..

Length of procedure *(hh.mm)* ☐☐ . ☐☐

Stents removed *(0= no, 1= yes)* ☐

If yes, number of stents removed ☐

Side of stent insertion: Left *(0= no, 1= yes)* ☐

Side of stent insertion: Right ventral *(0= no, 1= yes)* ☐

Side of stent insertion: Right dorsal *(0= no, 1= yes)* ☐

Number of stents inserted ☐

Hospitalized *(0= no, 1= yes)* ☐

If yes from *(dd/mm/yyyy)* ____ till *(dd/mm/yyyy)* ____

Institute _____ Patient number ____ Patient verification code ____

Please return within one month after index drainage to: Antoni van Leeuwenhoek datacenter, Post Box 90203, 1006 BE Amsterdam

ADVERSE EVENTS

Were there any drainage related complications *(period: index procedure until re-drainage or explorative laparotomy)* *(0=no, 1=yes)* ☐

Record the worst grade that occurred according to CTC 4.0

Adverse Event	*Grade*	*Relation to procedure* ***(a)***	*SAE* ***(b)***
1. Cholangitis	☐	☐	☐
2. Acute cholecystitis	☐	☐	☐
3. Acute pancreatitis	☐	☐	☐
4. Hemorrhage	☐	☐	☐
Specify location……			
5. Perforation	☐	☐	☐
Specify location……			
6. Portal vein thrombosis	☐	☐	☐
7. Dehydration	☐	☐	☐
8. Stent/catheter dysfunction	☐	☐	☐

Adverse Event	*Grade*	*Relation to procedure* ***(a)***	*SAE* ***(b)***
Other, **only use CTCAE 4.0 terminology**			
15. specify……	☐	☐	☐
16. specify……	☐	☐	☐
17. specify……	☐	☐	☐
18. specify……	☐	☐	☐
19. specify……	☐	☐	☐
20. specify……	☐	☐	☐

(a)
1= unrelated
2= unlikely
3= possible
4= probable
5= certain / definite

(b)
0= no
1= yes

INTERVENTIONS AFTER INDEX DRAINAGE PROCEDURE

Percutaneous intervention (other than PTBD) *(0=no, 1=yes)* ☐

If yes, date *(dd/mm/yyyy)* ____

Laparotomy intervention *(not including planned explorative laparotomy)* *(0=no, 1=yes)* ☐

If yes, date *(dd/mm/yyyy)* ____

ICU management *(0=no, 1=yes)* ☐

If yes, date *(dd/mm/yyyy)* ____

Drainage

index drainage procedure = iPTBD

Protocol version: 3.0 Feb 2014
CRF version: 2.0 Jun 2014

Institute _____ Patient number ____ Patient verification code ____

Please return within one month after index drainage to: Antoni van Leeuwenhoek datacenter, Post Box 90203, 1006 BE Amsterdam

Date of iPTBD procedure *(dd/mm/yyyy)* ____

PROCEDURE CHARACTERISTICS

Standard antibiotics prophylaxis *(0= no, 1= yes)* ☐

Antibiotics given ☐
1= 2000 mg ceftriaxone + 5 mg/kg gentamycin
2= 2000 mg ceftriaxone alone
3= 1200 mg Augmentin
8= other, specify……

Internal drainage through stenosis successful *(0= no, 1= yes)* ☐
(internal + external drainage)

If no, reason ☐
1= procedure discontinued before stent placement.
2= unable to cannulate proximal bile ducts
3= unable to cannulate obstruction.
4= planned two-stage procedure
8= other, specify……..

Length of procedure *(hh.mm)* ☐☐ . ☐☐

Side of catheter insertion: left *(0= no, 1= yes)* ☐

Side of catheter insertion: right ventral *(0= no, 1= yes)* ☐

Side of catheter insertion: right dorsal *(0= no, 1= yes)* ☐

Number of catheters inserted ☐

Hospitalized from *(dd/mm/yyyy)* ____ till *(dd/mm/yyyy)* ____

Drainage

index drainage procedure = iPTBD

Protocol version: 3.0 Feb 2014
CRF version: 2.0 Jun 2014

Institute _____ Patient number ____ Patient verification code ____

Please return within one month after index drainage to: Antoni van Leeuwenhoek datacenter, Post Box 90203, 1006 BE Amsterdam

ADVERSE EVENTS

Were there any drainage related complications *(period: index procedure until re-drainage or explorative laparotomy)* *(0=no, 1=yes)* ☐

Record the worst grade that occurred according to CTC 4.0

Adverse Event	*Grade*	*Relation to procedure* ***(a)***	*SAE* ***(b)***
1. Cholangitis	☐	☐	☐
2. Acute cholecystitis	☐	☐	☐
3. Acute pancreatitis	☐	☐	☐
4. Hemorrhage	☐	☐	☐
Specify location……			
5. Perforation	☐	☐	☐
Specify location……			
6. Portal vein thrombosis	☐	☐	☐
7. Dehydration	☐	☐	☐
8. Stent/catheter dysfunction	☐	☐	☐

(a)
1= unrelated
2= unlikely
3= possible
4= probable
5= certain / definite

(b)
0= No
1= Yes

Adverse Event	*Grade*	*Relation to procedure* ***(a)***	*SAE* ***(b)***
Other, **only use CTCAE 4.0 terminology**			
15. specify……	☐	☐	☐
16. specify……	☐	☐	☐
17. specify……	☐	☐	☐
18. specify……	☐	☐	☐
19. specify……	☐	☐	☐
20. specify……	☐	☐	☐

INTERVENTIONS AFTER INDEX DRAINAGE PROCEDURE

Percutaneous intervention (other than PTBD) *(0=no, 1=yes)* ☐

If yes, date *(dd/mm/yyyy)* ____

Laparotomy intervention *(not including planned explorative laparotomy)* *(0=no, 1=yes)* ☐

If yes, date *(dd/mm/yyyy)* ____

ICU management *(0=no, 1=yes)* ☐

If yes, date *(dd/mm/yyyy)* ____

Drainage

re-drainage procedure = rEBD

Institute _____ Patient number ____ Patient verification code ____

Please return within one month after randomization to: Antoni van Leeuwenhoek datacenter, Post Box 90203, 1006 BE Amsterdam

Date of rEBD procedure *(dd/mm/yyyy)* ____

Indication of drainage procedure ____
1= technical failure of previous procedure
2= therapeutic failure previous procedure
3= cholangitis
4= stent dysfunction
5= portal vein embolisation (PVE)
8= other, specify……..

PROCEDURE CHARACTERISTICS

Standard antibiotics prophylaxis *(0= no, 1= yes)* ____

Antibiotic treatment cholangitis *(0= no, 1= yes)* ____

Antibiotics given ____
1= 2000 mg ceftriaxone + 5 mg/kg gentamycin
2= 2000 mg ceftriaxone alone
3= 1200 mg Augmentin
8= other, specify……

Standard post-ERCP NSAID suppository *(100 mg Diclofenac)* *(0= no, 1= yes)* ____

Sphincterotomy *(0= no, 1= yes, 2= sphincterotomy performed in earlier stage)* ____

Stent placement through stenosis successful *(0= no, 1= yes)* ____

If no, reason ____
1= procedure discontinued before stent placement.
2= unable to cannulate obstruction.
8= other, specify……..

Length of procedure *(hh.mm)* ____ . ____

Stents removed *(0= no, 1= yes)* ____

If yes, number of stents removed ____

Side of stent insertion: Left *(0= no, 1= yes)* ____

Side of stent insertion: Right ventral *(0= no, 1= yes)* ____

Side of stent insertion: Right dorsal *(0= no, 1= yes)* ____

Number of stents inserted ____

Hospitalized *(0= no, 1= yes)* ____

If yes from *(dd/mm/yyyy)* ____ till *(dd/mm/yyyy)* ____

Drainage

re-drainage procedure = rEBD

Institute _____ Patient number ____ Patient verification code ____

Please return within one month after randomization to: Antoni van Leeuwenhoek datacenter, Post Box 90203, 1006 BE Amsterdam

Date of rEBD procedure *(dd/mm/yyyy)* ____

ADVERSE EVENTS

Were there any drainage related complications *(period: re-drainage untill re-drainage or explorative laparotomy)* *(0=no, 1=yes)* ☐

Record the worst grade that occurred according to CTC 4.0

Adverse Event	*Grade*	*Relation to procedure* ***(a)***	*SAE* ***(b)***
1. Cholangitis	☐	☐	☐
2. Acute cholecystitis	☐	☐	☐
3. Acute pancreatitis	☐	☐	☐
4. Hemorrhage	☐	☐	☐
Specify location……			
5. Perforation	☐	☐	☐
Specify location……			
6. Portal vein thrombosis	☐	☐	☐
7. Dehydration	☐	☐	☐
8. Stent/catheter dysfunction	☐	☐	☐

Adverse Event	*Grade*	*Relation to procedure* ***(a)***	*SAE* ***(b)***
Other, **only use CTCAE 4.0 terminology**			
15. specify……	☐	☐	☐
16. specify……	☐	☐	☐
17. specify……	☐	☐	☐
18. specify……	☐	☐	☐
19. specify……	☐	☐	☐
20. specify……	☐	☐	☐

(a)
1= unrelated
2= unlikely
3= possible
4= probable
5= certain / definite

(b)
0= No
1= Yes

INTERVENTIONS AFTER RE-DRAINAGE PROCEDURE

Percutaneous intervention (other than PTBD) *(0=no, 1=yes)* ☐

If yes, date *(dd/mm/yyyy)* ____

Laparotomy intervention *(not including planned explorative laparotomy)* *(0=no, 1=yes)* ☐

If yes, date *(dd/mm/yyyy)* ____

ICU management *(0=no, 1=yes)* ☐

If yes, date *(dd/mm/yyyy)* ____

ANTONI VAN LEEUWENHOEK
NEDERLANDS KANKER INSTITUUT

Drainage

re-drainage procedure = rPTBD

Protocol version: 3.0 Feb 2014
CRF version: 2.0 Jun 2014

Institute _____ Patient number ____ Patient verification code ____

Please return within one month after randomization to: Antoni van Leeuwenhoek datacenter, Post Box 90203, 1006 BE Amsterdam

Date of rPTBD procedure *(dd/mm/yyyy)* ____

Indication of drainage procedure ____
1= technical failure of previous procedure
2= therapeutic failure previous procedure
3= cholangitis
4= stent dysfunction
5= portal vein embolisation (PVE)
8= other, specify……..

PROCEDURE CHARACTERISTICS

Standard antibiotics prophylaxis *(0= no, 1= yes)* ____

Antibiotic treatment cholangitis *(0= no, 1= yes)* ____

Antibiotics given ____
1= 2000 mg ceftriaxone + 5 mg/kg gentamycin
2= 2000 mg ceftriaxone alone
3= 1200 mg Augmentin
8= other, specify……

Internal drainage through stenosis succesfull *(0= no, 1= yes)* ____
(internal + external drainage)

If no, reason ____
1= procedure discontinued before stent placement.
2= unable to cannulate proximal bile ducts
3= unable to cannulate obstruction.
4= planned two-stage procedure
8= other, specify……..

Length of procedure *(hh.mm)* ____ . ____

Catheter replacement: *(0= no, 1= yes)* ____

Side of catheter replacement: left *(0= no, 1= yes)* ____

Side of catheter replacement: right ventral *(0= no, 1= yes)* ____

Side of catheter replacement: right dorsal *(0= no, 1= yes)* ____

New catheter insertion: *(0= no, 1= yes)* ____

Side of new catheter insertion: left *(0= no, 1= yes)* ____

Side of new catheter insertion: right ventral *(0= no, 1= yes)* ____

Side of new catheter insertion: right dorsal *(0= no, 1= yes)* ____

Total number of catheters inserted ____

Hospitalized from *(dd/mm/yyyy)* ____ till *(dd/mm/yyyy)* ____

ANTONI VAN LEEUWENHOEK
NEDERLANDS KANKER INSTITUUT

Drainage

re-drainage procedure = rPTBD

Protocol version: 3.0 Feb 2014
CRF version: 2.0 Jun 2014

Institute _____ Patient number ____ Patient verification code ____

Please return within one month after randomization to: Antoni van Leeuwenhoek datacenter, Post Box 90203, 1006 BE Amsterdam

Date of rPTBD procedure *(dd/mm/yyyy)* ____

ADVERSE EVENTS

Were there any drainage related complications *(period: re-drainage untill re-drainage or resection)* *(0=no, 1=yes)* ☐

Record the worst grade that occurred according to CTC 4.0

Adverse Event	*Grade*	*Relation to procedure* ***(a)***	*SAE* ***(b)***
1. Cholangitis	☐	☐	☐
2. Acute cholecystitis	☐	☐	☐
3. Acute pancreatitis	☐	☐	☐
4. Hemorrhage	☐	☐	☐
Specify location……			
5. Perforation	☐	☐	☐
Specify location……			
6. Portal vein thrombosis	☐	☐	☐
7. Dehydration	☐	☐	☐
8. Stent/catheter dysfunction	☐	☐	☐

Adverse Event	*Grade*	*Relation to procedure* ***(a)***	*SAE* ***(b)***
Other, **only use CTCAE 4.0 terminology**			
15. specify……	☐	☐	☐
16. specify……	☐	☐	☐
17. specify……	☐	☐	☐
18. specify……	☐	☐	☐
19. specify……	☐	☐	☐
20. specify……	☐	☐	☐

(a)
1= unrelated
2= unlikely
3= possible
4= probable
5= certain / definite

(b)
0= No
1= Yes

INTERVENTIONS AFTER RE-DRAINAGE PROCEDURE

Percutaneous intervention (other than PTBD) *(0=no, 1=yes)* ☐

If yes, date *(dd/mm/yyyy)* ____

Laparotomy intervention *(not including planned explorative laparotomy)* *(0=no, 1=yes)* ☐

If yes, date *(dd/mm/yyyy)* ____

ICU management *(0=no, 1=yes)* ☐

If yes, date *(dd/mm/yyyy)* ____

ANTONI VAN LEEUWENHOEK
NEDERLANDS KANKER INSTITUUT

Drainage
Evaluation

Protocol version: 3.0 Feb 2014
CRF version: 2.0 Jun 2014

Institute | Patient number | Patient verification code

Please return within one month after laparotomy to: Antoni van Leeuwenhoek datacenter, Post Box 90203, 1006 BE Amsterdam

Evaluation of total bilirubin levels

	Date *dd/mm/yyyy*	result *µmol/l*
Bilirubin prior to referral *(also prior to first drainage elsewhere)*		
Bilirubin at randomization		
Bilirubin 7 days after technical success		
Bilirubin 14 days after technical success		
Bilirubin preoperatively		

Evaluation of therapeutic success *7 days after technical success*

Was 7-day evaluation performed
0=no
1=yes, after iEBD/iPTBD
2=yes, after rEBD/rPTBD

If yes, please specify

Reduced bile ducts in segments FRL on ultrasound *(0= no, 1= yes)*

Was therapeutic success achieved *(0= no, 1= yes)*
(defined as: ≥ 20% decrease relative to reference bilirubin and decreased bile ducts in FRL)

Re-drainage procedures necessary *(0= no, 1= yes)*
If yes, complete re-drainage procedure pages (rEBD or rPTBD)

Cross over to other drainage procedure *(0= no, 1= yes)*

Number of drainage procedures done between randomization and laparotomy

Drainage

Explorative laparotomy

Institute | Patient number | Patient verification code

Please return within one month after laparotomy to: Antoni van Leeuwenhoek datacenter, Post Box 90203, 1006 BE Amsterdam

Date index drainage procedure *(dd/mm/yyyy)*

Portal vein embolization *(0= no, 1= yes)*

Number of drainage procedures after randomization

Date of preoperative bilirubin measurement *(dd/mm/yyyy)*

Preoperative bilirubin (max 2 days before surgery) *(µmol/l)* .

Date of explorative laparotomy *(dd/mm/yyyy)*

Operation date as planned *(0= no, 1= yes)*

If no reason of delay
1= rescheduled for clinical reasons (patient's condition did not allow surgery)
2= rescheduled for organizational reasons

Antibiotic prophylaxis *(0= no, 1= yes)*

Details	Administration *1= oral 2= IV*	daily dose *(mg)*	Start date *(dd/mm/yyyy)*	End date *(dd/mm/yyyy)*
1.				
2.				
3.				

Resection of the tumor performed *(0= no, 1= yes)*

If no, reason irresectability
1= metastases
2= loco regional ingrowth
9= unknown

Palliative procedures during surgery
1= none
2= cholecystectomy
8= other, specify.....

If yes, type of liver resection
1= local resection
2= local + hilus resection
3= left sided hepatectomy, specify
1= 3 segments (hemihepatectomy)
2= 4-5 segments (extended hemihepatectomy)
4= right sided hepatectomy, specify
1= 4 segments (hemihepatectomy)
2= 5 segments (extended hemihepatectomy)
8= other, specify.....

Drainage

Explorative laparotomy

Institute | Patient number | Patient verification code

Please return within one month after laparotomy to: Antoni van Leeuwenhoek datacenter, Post Box 90203, 1006 BE Amsterdam

Segment 1 (lobus caudatus) resected *(0= no, 1= yes)* ☐

Remnant liver after resection

Left liver segments *(0= no, 1= yes)* ☐

Right ventral segments *(0= no, 1= yes)* ☐

Right dorsal segments *(0= no, 1= yes)* ☐

Portal vein reconstruction *(0= no, 1= yes)* ☐

Number of created hepaticojejunostomies ☐

With a transanastomotic PTBD drain ☐

Without a transanastomotic PTBD drain ☐

Fill out irrespective of resectability

Length of procedure *(hh.mm)* ☐☐ . ☐☐

Blood loss *(ml)* ☐☐☐☐

Perioperative blood transfusion *(packed cells)* ☐☐

Pringle manoeuvre *(clamping of the hepatoduodenal ligament)* *(0= no, 1= yes)* ☐

If yes *(1= continuous, 2= intermittent)* ☐

Total clamping time *(min)* ☐☐

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INTERVENTIONS AFTER LAPAROTOMY

Percutaneous intervention (other than PTBD) *(0=no, 1=yes)*

If yes, date *(dd/mm/yyyy)*

Re- Laparotomy *(0=no, 1=yes)*

If yes, date *(dd/mm/yyyy)*

ICU management *(0=no, 1=yes)*

If yes, date *(dd/mm/yyyy)*

PATHOLOGY

Histology *(1=benigne disease, 2= malignant disease)*

If malignant

Tumor differentiation grade *(1=well differentiated, 2= poor differentiated)*

Histology *(1=sclerosing, 2= papillary)*

Resection margins *(0= R0, 1= R1, 2= R2)*

TNM STAGING

T *(0= T0, 1= T1, 2= T2, 3= T3, 4= T4, 5= Tis, 9= Tx)*

N *0= N0, 1=N1, 2= N2, 3= N3, 9= Nx*

M *(0= M0,1= M1,9= Mx)*

Endoscopic versus percutaneous biliary drainage in resectable perihilar cholangiocarcinoma:

ANTONI VAN LEEUWENHOEK
NEDERLANDS KANKER INSTITUUT

Drainage

final follow up

Protocol version: 3.0 Feb 2014
CRF version: 2.0 Jun 2014

Institute _____ Patient number ____ Patient verification code ____

Please return within one month after final follow up to: Antoni van Leeuwenhoek datacenter, Post Box 90203, 1006 BE Amsterdam

Final follow up to be done 90 days after explorative laparotomy

Date follow up *(dd/mm/yyyy)* ____

CLINICAL ASSESSMENT

Patient status *(1= alive, 2= dead)* ____

If "dead" (2), please specify cause of death: ____

1= protocol cancer
2= second malignancy
3= toxicity
4= cardiovascular
8= other, specify……...

Was patient admitted to (another) hospital for a post-operative complication *(0= no, 1= yes)* ____

If yes, date admission *(dd/mm/yyyy)* ____

Date discharge *(dd/mm/yyyy)* ____

Indication for re-admission ____

1= recurrent disease
2= biliary leakage
3= wound infection
4= portal vein thrombosis
5= emergency relaparotomy
6= pneumonia
8= other, specify……..

INTERVENTIONS

Endoscopic intervention *(0=no, 1=yes)* ____

If yes, date *(dd/mm/yyyy)* ____

Percutaneous intervention *(0=no, 1=yes)* ____

If yes, date *(dd/mm/yyyy)* ____

Laparotomy intervention *(0=no, 1=yes)* ____

If yes, date *(dd/mm/yyyy)* ____

ICU management *(0=no, 1=yes)* ____

If yes, date *(dd/mm/yyyy)* ____

Drainage

final follow up

Protocol version: 3.0 Feb 2014
CRF version: 2.0 Jun 2014

Institute _____ Patient number ____ Patient verification code ____

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Final follow up to be done 90 days after explorative laparotomy

ADVERSE EVENTS

Were there any post-operative complications? *(0=no, 1=yes)* ☐

Record the worst grade that occurred according to CTC 4.0

Adverse Event	*Grade*	*Relation to procedure* ***(a)***	*SAE* ***(b)***
1. Cholangitis	☐	☐	☐
2. Acute cholecystitis	☐	☐	☐
3. Acute pancreatitis	☐	☐	☐
4. Hemorrhage	☐	☐	☐
Specify location……			
5. Perforation	☐	☐	☐
Specify location……			
6. Portal vein thrombosis	☐	☐	☐
7. Dehydration	☐	☐	☐
8. Stent dysfunction	☐	☐	☐
9. Hepaticojejunostomy (biliary) leakage	☐	☐	☐
10. Intra-abdominal abscess formation	☐	☐	☐

Adverse Event	*Grade*	*Relation to procedure* ***(a)***	*SAE* ***(b)***
11. Wound infection	☐	☐	☐
12. (emergency) (re) laparotomy	☐	☐	☐
13. Pneumonia	☐	☐	☐
14. Postresectional liver failure	☐	☐	☐
Other, **only use CTCAE 4.0 terminology**			
15. specify……	☐	☐	☐
16. specify……	☐	☐	☐
17. specify……	☐	☐	☐
18. specify……	☐	☐	☐
19. specify……	☐	☐	☐
20. specify……	☐	☐	☐

(a)
1= unrelated
2= unlikely
3= possible
4= probable
5= certain / definite

(b)
0= No
1= Yes

Primary endpoint based on reported adverse events verified with local researcher? *(0=no, 1=yes)* ☐

SIGNATURE INVESTIGATOR

I certify that I have reviewed the data on this Case Report Form and that all information is complete and accurate.

Investigator's name …… Investigator's signature …… Date*(dd/mm/yyyy)* ____