

Obsidian ASG Autologous Platelet-Rich Fibrin Matrix for the prevention of postoperative pancreatic fistula following pancreatic resection: study protocol for a feasibility trial

CASE REPORT FORM

Principal Investigator

Prof. Dr.med Oliver Strobel

Investigators

PD Dr. med. Ulla Klaiber

Dr. med. Charlotte Gustorff

KKS - Clinical Trials Coordination Centre

Währinger Straße 25a, OG 1

1090 Vienna Austria

Tel.: +43 (0)1 40160 - 25176

kks@meduniwien.ac.at

Division of Visceral Surgery, Department of General Surgery

Medical University of Vienna

Währinger Gürtel 18-20

1090 Vienna, Austria

Obsidian-Pilottrial

Visit 1: Screening/Enrolment

Screening No.: _____

Year of birth: _____

Date of screening: _____ (dd/mm/yyyy)

Inclusion criteria	yes	no
1. Age ≥18 years	<input type="radio"/>	<input type="radio"/>
2. Patient undergoing elective partial pancreatic resection for any reason	<input type="radio"/>	<input type="radio"/>
3. Ability to understand character and individual consequences of the trial	<input type="radio"/>	<input type="radio"/>
4. Written informed consent	<input type="radio"/>	<input type="radio"/>
5. Date of written informed consent:	<input type="radio"/>	<input type="radio"/>

Exclusion criteria	yes	no
1. ASA score > III	<input type="radio"/>	<input type="radio"/>
2. Pregnancy or lactation	<input type="radio"/>	<input type="radio"/>
3. Understanding or language problems	<input type="radio"/>	<input type="radio"/>
4. Inability to comply with study and/or follow-up procedures	<input type="radio"/>	<input type="radio"/>
5. Known hypersensitivity to any component of the formulation	<input type="radio"/>	<input type="radio"/>
6. Concurrent participation in another interventional clinical trial	<input type="radio"/>	<input type="radio"/>

Demography

Gender ☐ female ☐ male ☐ divers

Age: _____ years

Anamnesis

Body height and weight: _____ cm _____ kg

Previous abdominal surgery

Previous radio-/chemotherapy within the last 6 months

Relevant comorbidities:

-

Coronary heart disease☐

-

Congestive heart failure NYHA I/II☐

-

Chronic atrial fibrillation☐

-

Chronic renal insufficiency☐

-

Chronic obstructive pulmonary disease (COPD)☐

-

Diabetes mellitus ☐

-

Other:☐ _____

ASA-classification: ☐ I (healthy patient)☐ II (mild systemic disease)
☐ III (severe systemic disease)

Pancreas-specific anamnesis

Indication for the planned surgical procedure

-

Pancreatic carcinoma

-

Cystic neoplasm

-

Neuroendocrine tumor

-

Other: _____

If preexisting diabetes mellitus, insulin dependent? Yes ☐ no ☐

Preexisting exocrine pancreatic insufficiency? Yes ☐ no ☐

○

<h1>Obsidian-Pilottrial</h1>		<h2>Visit 2: Surgery</h2>
Screening No.: _____		Year of birth: _____
Date of surgery _____		
Performed surgery - DP <input type="checkbox"/> PD <input type="checkbox"/> other <input type="checkbox"/> _____		
Approach - Laparoscopic <input type="checkbox"/> robotic <input type="checkbox"/> open <input type="checkbox"/> - Conversion: no <input type="checkbox"/> yes <input type="checkbox"/> , reason for conversion _____		
Level of pancreatic transection - above <input type="checkbox"/> left to portal vein <input type="checkbox"/> right to portal vein <input type="checkbox"/>		
Transsection technique: _____		
Closure technique: _____		
Anastomosis technique _____		
Texture of pancreatic tissue: - soft <input type="checkbox"/> intermediate <input type="checkbox"/> hard <input type="checkbox"/>		
Pancreatic ducts size: _____ (mm)		
Additional resections: splenectomy <input type="checkbox"/> lymphadenectomy <input type="checkbox"/> others <input type="checkbox"/> _____		
Duration from skin incision to closure: _____ min		
Intraoperative blood loss: _____ ml		
Intraoperative blood transfusion: _____ ml		
Placement of abdominal drain: yes <input type="checkbox"/> no <input type="checkbox"/>		
Administration of somatostatin-analogues: - during surgery: yes <input type="checkbox"/> no <input type="checkbox"/> - after surgery: yes <input type="checkbox"/> no <input type="checkbox"/>		
Serious adverse events (new events since last visit) Were there any serious adverse events? Yes <input type="checkbox"/> no <input type="checkbox"/> Were there any other intervention related side effects? Yes <input type="checkbox"/> no <input type="checkbox"/> If yes, please specify: _____		
Protocol violations Were there any protocol violations? Yes <input type="checkbox"/> no <input type="checkbox"/> If yes, please specify: _____		

Obsidian-Pilottrial		Visit 3: POD 3
Screening No.: _____		Year of birth: _____
Date of visit: _____ (dd/mm/yyyy)		
Assessment of postoperative pancreatic fistula Pancreatic amylase at POD3: _____ (U/L) Lipase at POD3: _____ (U/L) Classification of POPF: no POPF <input type="checkbox"/> grade A <input type="checkbox"/> grade B <input type="checkbox"/> grade C <input type="checkbox"/>		
Complications (new events since last visit) Perioperative sepsis <input type="checkbox"/> Postpancreatectomy acute pancreatitis <input type="checkbox"/> - associated complications (e.g. bleeding or perforation) <input type="checkbox"/> please, specify: _____ Delayed gastric emptying Post-pancreatectomy hemorrhage: no PPH <input type="checkbox"/> grade A <input type="checkbox"/> grade B <input type="checkbox"/> grade C <input type="checkbox"/> Intraabdominal fluid collection <input type="checkbox"/> Intraabdominal abscess <input type="checkbox"/> Lymphatic fistula / chylus ascites <input type="checkbox"/> Wound infection <input type="checkbox"/> Burst abdomen <input type="checkbox"/>		
Reinterventions / - operations <input type="checkbox"/> _____		
ICU stay <input type="checkbox"/> Transfer to normal ward at _____. POD		
Diagnostics/interventions: yes <input type="checkbox"/> no <input type="checkbox"/> CT-scan <input type="checkbox"/> Interventional application of drainage <input type="checkbox"/> Relaparotomy <input type="checkbox"/> , state the reason: _____		
Serious adverse events (new events since last visit) Were there any serious adverse events? Yes <input type="checkbox"/> no <input type="checkbox"/> Were there any other intervention related side effects? Yes <input type="checkbox"/> no <input type="checkbox"/> If yes, please specify: _____		
Protocol violations Were there any protocol violations? Yes <input type="checkbox"/> no <input type="checkbox"/> If yes, please specify: _____		

Obsidian-Pilottrial		Visit 4: POD 7
Screening No.: _____		Year of birth: _____
Date of visit: _____ (dd/mm/yyyy)		
Assessment of postoperative pancreatic fistula Pancreatic amylase at POD7: _____ (U/L) Lipase at POD7: _____ (U/L) Classification of POPF: no POPF <input type="checkbox"/> grade A <input type="checkbox"/> grade B <input type="checkbox"/> grade C <input type="checkbox"/>		
Complications (new events since last visit) Perioperative sepsis <input type="checkbox"/> Postpancreatectomy acute pancreatitis <input type="checkbox"/> - associated complications (e.g. bleeding or perforation) <input type="checkbox"/> please, specify: _____ Delayed gastric emptying Post-pancreatectomy hemorrhage: no PPH <input type="checkbox"/> grade A <input type="checkbox"/> grade B <input type="checkbox"/> grade C <input type="checkbox"/> Intraabdominal fluid collection <input type="checkbox"/> Intraabdominal abscess <input type="checkbox"/> Lymphatic fistula / chylus ascites <input type="checkbox"/> Wound infection <input type="checkbox"/> Burst abdomen <input type="checkbox"/>		
Reinterventions / - operations <input type="checkbox"/> _____		
ICU stay <input type="checkbox"/> Transfer to normal ward at _____. POD		
Diagnostics/interventions: yes <input type="checkbox"/> no <input type="checkbox"/> CT-scan <input type="checkbox"/> Interventional application of drainage <input type="checkbox"/> Relaparotomy <input type="checkbox"/> , state the reason: _____		
Serious adverse events (new events since last visit) Were there any serious adverse events? Yes <input type="checkbox"/> no <input type="checkbox"/> Were there any other intervention related side effects? Yes <input type="checkbox"/> no <input type="checkbox"/> If yes, please specify: _____		
Protocol violations Were there any protocol violations? Yes <input type="checkbox"/> no <input type="checkbox"/> If yes, please specify: _____		

Obsidian-Pilottrial		Visit 5: POD 14/day of discharge
Screening No.: _____		Year of birth: _____
Date of visit: _____ (dd/mm/yyyy)		
Assessment of postoperative pancreatic fistula		
Classification of POPF: no POPF <input type="checkbox"/> grade A <input type="checkbox"/> grade B <input type="checkbox"/> grade C <input type="checkbox"/>		
Complications (new events since last visit)		
Perioperative sepsis <input type="checkbox"/>		
Postpancreatectomy acute pancreatitis <input type="checkbox"/>		
- associated complications (e.g. bleeding or perforation) <input type="checkbox"/> please, specifiy: _____		
Delayed gastric emptying		
Post-pancreatectomy hemorrhage: no PPH <input type="checkbox"/> grade A <input type="checkbox"/> grade B <input type="checkbox"/> grade C <input type="checkbox"/>		
Intraabdominal fluid collection <input type="checkbox"/>		
Intraabdominal abscess <input type="checkbox"/>		
Lymphatic fistula / chylus ascites <input type="checkbox"/>		
Wound infection <input type="checkbox"/>		
Burst abdomen <input type="checkbox"/>		
Reinterventions / - operations <input type="checkbox"/> _____		
ICU stay <input type="checkbox"/>		
Transfer to normal ward at _____. POD		
Diagnostics/interventions: yes <input type="checkbox"/> no <input type="checkbox"/>		
CT-scan <input type="checkbox"/>		
Interventional application of drainage <input type="checkbox"/>		
Relaparotomy <input type="checkbox"/> , state the reason: _____		
Serious adverse events (new events since last visit)		
Were there any serious adverse events? Yes <input type="checkbox"/> no <input type="checkbox"/>		
Were there any other intervention related side effects? Yes <input type="checkbox"/> no <input type="checkbox"/>		
If yes, please specify: _____		
Protocol violations		
Were there any protocol violations? Yes <input type="checkbox"/> no <input type="checkbox"/>		
If yes, please specify: _____		

Obsidian-Pilottrial		Visit 6: POD 30
Screening No.: _____		Year of birth: _____
Date of visit: _____ (dd/mm/yyyy)		
Assessment of postoperative pancreatic fistula		
Classification of POPF: no POPF <input type="checkbox"/> grade A <input type="checkbox"/> grade B <input type="checkbox"/> grade C <input type="checkbox"/>		
Complications (new events since last visit)		
Perioperative sepsis <input type="checkbox"/>		
Postpancreatectomy acute pancreatitis <input type="checkbox"/>		
- associated complications (e.g. bleeding or perforation) <input type="checkbox"/> please, specifiy: _____		
Delayed gastric emptying		
Post-pancreatectomy hemorrhage: no PPH <input type="checkbox"/> grade A <input type="checkbox"/> grade B <input type="checkbox"/> grade C <input type="checkbox"/>		
Intraabdominal fluid collection <input type="checkbox"/>		
Intraabdominal abscess <input type="checkbox"/>		
Lymphatic fistula / chylus ascites <input type="checkbox"/>		
Wound infection <input type="checkbox"/>		
Burst abdomen <input type="checkbox"/>		
Reinterventions / - operations <input type="checkbox"/> _____		
ICU stay <input type="checkbox"/>		
Transfer to normal ward at _____. POD		
Diagnostics/interventions: yes <input type="checkbox"/> no <input type="checkbox"/>		
CT-scan <input type="checkbox"/>		
Interventional application of drainage <input type="checkbox"/>		
Relaparotomy <input type="checkbox"/> , state the reason: _____		
Serious adverse events (new events since last visit)		
Were there any serious adverse events? Yes <input type="checkbox"/> no <input type="checkbox"/>		
Were there any other intervention related side effects? Yes <input type="checkbox"/> no <input type="checkbox"/>		
If yes, please specify: _____		
Protocol violations		
Were there any protocol violations? Yes <input type="checkbox"/> no <input type="checkbox"/>		
If yes, please specify: _____		

Obsidian-Pilottrial		Visit 7: POD 90 / premature study termination
Screening No.: _____		Year of birth: _____
Date of visit: _____ (dd/mm/yyyy)		
Assessment of postoperative pancreatic fistula Lipase at POD3: _____ (U/L) Classification of POPF: no POPF <input type="checkbox"/> grade A <input type="checkbox"/> grade B <input type="checkbox"/> grade C <input type="checkbox"/>		
Complications (new events since last visit) Perioperative sepsis <input type="checkbox"/> Postpancreatectomy acute pancreatitis <input type="checkbox"/> - associated complications (e.g. bleeding or perforation) <input type="checkbox"/> please, specify: _____ Delayed gastric emptying Post-pancreatectomy hemorrhage: no PPH <input type="checkbox"/> grade A <input type="checkbox"/> grade B <input type="checkbox"/> grade C <input type="checkbox"/> Intraabdominal fluid collection <input type="checkbox"/> Intraabdominal abscess <input type="checkbox"/> Lymphatic fistula / chylus ascites <input type="checkbox"/> Wound infection <input type="checkbox"/> Burst abdomen <input type="checkbox"/>		
Reinterventions / - operations <input type="checkbox"/> _____		
ICU stay <input type="checkbox"/> Transfer to normal ward at _____. POD		
Diagnostics/interventions: yes <input type="checkbox"/> no <input type="checkbox"/> CT-scan <input type="checkbox"/> Interventional application of drainage <input type="checkbox"/> Relaparotomy <input type="checkbox"/> , state the reason: _____		
Serious adverse events (new events since last visit) Were there any serious adverse events? Yes <input type="checkbox"/> no <input type="checkbox"/> Were there any other intervention related side effects? Yes <input type="checkbox"/> no <input type="checkbox"/> If yes, please specify: _____		
Protocol violations Were there any protocol violations? Yes <input type="checkbox"/> no <input type="checkbox"/> If yes, please specify: _____		
Hospitalization Date of discharge: _____ or hospital stay ongoing <input type="checkbox"/> Total intensive care unit stay (postoperative and readmissions): ____ (days) Total hospital stay: ____ (days)		
Results from final histological examination Pancreatic carcinoma <input type="checkbox"/> - if yes, please enter pTNM-stage: _____ Cystic neoplasm <input type="checkbox"/> Neuroendocrine tumor <input type="checkbox"/> Other <input type="checkbox"/> _____		
I confirm that all data entered in this CRF is complete and accurate to the		

best of my knowledge.

X

date, investigator's name (block letters)