Country: Town:

Hospital:

Doctor:

**ADMISSION DATE AND TIME:**

**ELEFANT NUMBER:**

**Questionnaire**

**1. Patient personal details**

Insurance number:………………………………………………………………………..
First name:……………………………………………………………………………………..
Last name: …………………………………………………………………………………….
Date of birth:………………………………………………………………………………….
Gender: female male

Ethnicity/Race: White / Black / Asian-Indian Not known

**2. Inclusion criteria**

**Age 18 to 80 years** : YES NO
**Diagnosed acute pancreatitis**\*: YES NO
**TG level is at least** 1000 mg/dl (11.3 mmol/L) : YES NO
**Signed informed consent** : YES NO
One „NO” is present = DO NOT INCLUDE!

**3. Exclusion criteria**

**Pregnancy or breast feeding** : YES NO
**Abdominal pain > 48 hours** : YES NO
**Coma** : YES NO
**Malignancy** : YES NO
**Early ARDS** : YES NO
**Renal failure** : YES NO
**Allergy to insulin or heparin** : YES NO
**Any reasons contraindicating plasmapheresis\*\*** : YES NO

One „YES” is present = EXCLUDE!

\*\*severe active bleeding or disseminated intravascular coagulation (htc level <20%), other forms of coagulopathy; hemodynamic instability; potassium plasma levels < 3.5 mEq/L, sepsis, allergy to albumin, serum calcium levels < 2.1 mmol/L (corrected calcium or ionized calcium); chronic heart failure (grade II or more of the NYHA or ejection fraction lower than 50%) or symptoms od fluid overload at recruitment, long QT syndrome.

**4. Details from the medical history**

* **Lipid metabolism disorder**: yes / no

if yes: type: ………………………………………………. since when (year):……………………………………….. Medications taken regulary for this condition: yes/no

if yes:

name:………..……………..active substance:…………..……………dose(gram,milligram, etc.)………………

* **Alcohol consumption**: yes / no

if yes: frequency: occasionally/monthly/weekly/dayly

amount (g/day):…………………………………

since when? (years):………………………….

Alcohol consumption in the last 2 weeks: …………………..

if not:

Did you drink alcohol earlier? yes/no

if yes: frequency: occasionally/monthly/weekly/daily

amount (g/occasion):…………………………………

For how many years?………………………………………

How long ago did you stop drinking alcohol?..........................

Guide for estimation of the amount:

1 dl beer (4.5 vol. %) = ~3.5 g alcohol

1 dl wine (12.5 vol. %) = ~10 g alcohol

1 dl hard drink (50 vol. %) = ~40 g alcohol

* **Smoking**: yes / no

if yes: amount (cigarettes/day):…………………

For how many years? …………………………

if not:

Did you smoke earlier? yes/no

if yes: amount (pcs/occasion):…………………………………

For how many years?………………………………………

How long ago did you stop smoking? ……………………………….

* **Drug abuse**: yes / no Prescribed medication should not be included here. if yes: type of drug:……………………………………. amount:…………………………………………. since when (year):……………………………
(if there are more drugs, please describe them in the NOTES section at the end)
* **Diabetes mellitus**: yes / no

if yes: type: Type I. / Type II./Type III. c / MODY

since when (year):……………………………

* **Any disease of the pancreas:** yes / no *Not counting the current episode.*

if yes: acute pancreatitis/ chronic pancreatitis/ autoimmune pancreatitis/ tumor/ other
if other: please describe: ……………………………………………………………

If the patient had ACUTE PANCREATITIS in the history:
How many times did the patient have acute episodes before this episode:...................................
When did the patient have the first acute episode (year):..............................................................

If the patient has CHRONIC/AUTOIMMUNE PANCREATITIS:
When was it diagnosed?..................................................................................................................
When did the patient have the first acute episode (year):................................................................
How many times did the patient have acute episodes before this episode:...................................

If the patient has PANCREATIC CANCER::
When was it diagnosed?..................................................................................................................
Was the patient diagnosed with chronic pancreatitis? yes / no / no data
If yes, when was it diagnosed?..........................................................................................................
When did the patient have the first acute episode (year):................................................................
Other information:............................................................................................................................

* **Other illnesses**: yes / no

if yes: hypertonia / stroke / dementia / chronic renal failure / chronic heart failure / other
if other: please list/describe:……………………………………………………………………………

* **Medications taken regularly**: yes / no

if yes:

name:………..……………..active substance:…………..……………dose(gram,milligram, etc.)……………… if fluid, concentration (e.g. 10%, 1g/2ml, etc.)…................... how many times per day (e.g. 3) type of administration:………………………………………………..other notes: ………………………………………

name:………..……………..active substance:…………..……………dose(gram,milligram, etc.)……………… if fluid, concentration (e.g. 10%, 1g/2ml, etc.)…................... how many times per day (e.g. 3) type of administration:………………………………………………..other notes: ………………………………………

name:………..……………..active substance:…………..……………dose(gram,milligram, etc.)……………… if fluid, concentration (e.g. 10%, 1g/2ml, etc.)… .................. how many times per day (e.g. 3) type of administration:………………………………………………..other notes: ………………………………………

* **Diet:** yes / no

if yes: diabetic / low fatty / vegetarianism / vegan / gluten free / latose free / milk free / paleo / other

if other: please specify:……………………

* **Family medical history:**

**Pancreas diseases in family:**  yes /no /no data

acute pancreatitis: yes /no /no data if yes, which relative:.............................\*

chronic pancreatitis: yes /no /no data if yes, which relative:.............................\*

autoimmune pancreatitis: yes /no /no data     if yes, which relative:.............................\*

pancreatic tumor: yes /no /no data      if yes, which relative:.............................\*

other:………………… yes /no /no data if yes, which relative:.............................\*

\*relationship to patient: mother/father/maternal grandmother/maternal grandfather/paternal grandmother/paternal grandfather/sister/brother/daughter/son/other

**5. Complains, symptoms**

**Abdominal pain**: yes / no

**if yes**: since when (hours):….………………………………………..

**type**: cramping / dull / sharp

**intensity (1-10**):……………………………………..

**location**: diffuse / localized

Please mark the location!

**radiation**:………………………………………………..

**6. Admission details and state**

**Blood pressure (Hgmm):**…………………… **Heart rate (/minute):**…………………………

**Body weight (kg):**……………………………… **Body height (cm):**…………………………………

**Respiratory rate (/minute):**………………. **Body temperature (axillary °C):** ……………………..

**Oxygen saturation (%):** …………………… **Previous O2 therapy**: yes/no

**Abdominal tenderness :** yes / no **Abdominal guarding:** yes / no

**Jaundice**: yes / no

**Glasgow Coma Scale (GCS):**……………………………………….

Eye response:
4 points: Spointsaneous eye opening
3 points: Eye opening in response any speech
2 points: Opening to response to pain
1 points: No eye opening

Motor Response:
6 points: Obeying command
5 points: Localizing response to pain
4 points: Withdraws to pain
3 points: Decorticate posture
2 points: Decerebrate posture
1 points: No verbal response

Verbal Response:
5 points: Oriented
4 points: Confused conversation
3 points: Inappropriate speech
2 points: Incomprehensible speech
1 points: No verbal response.

**7. Laboratory parameters**

**OBLIGATORY PARAMETERS:**

|  |  |
| --- | --- |
| Amylase (U/l)  |   |
| Lipase (U/l)  |   |
| White blood cell (WBC) count (G/l)  |   |
| Red blood cell (RBC) count (T/l)  |   |
| Hemoglobin (g/l)  |   |
| Hematocrit (%)  |   |
| Thrombocyte (G/l)  |   |
| Serum glucose (mmol/l)  |   |
| Hemoglobin A1C (%)  |   |
| Blood urea nitrogen (mmol/l)  |   |
| Creatinine (umol/l)  |   |
| eGFR  |   |
| C-reactive protein (mg/l)  |   |
| ASAT/GOT (U/l)  |   |
| Lactate dehydrogenase LDH (U/l)  |   |
| Calcium (mmol/l)  |   |
| Sodium (mmol/l)  |   |
| Potassium (mmol/l)  |   |
| Total protein (g/l)  |   |
| Albumin (g/l)  |   |
| Cholesterol (mmol/l)  |   |
| ALAT/GPT (U/l)  |   |
| Gamma GT (U/l)  |   |
| Total bilirubin (umol/l)  |   |
| Direct/Conjugated bilirubin (umol/l)  |   |
| Alkaline phosphatase (U/l)  |   |
| Procalcitonin (ng/ml)  |   |

**8. Imaging examinations**

* **Does the patient have pleural fluid:** yes / no / no data
* **Does the patient have lung infiltrate:** yes / no / no data
* **Does the patient have abnormal pancreatic structure:** yes / no / no data

if yes: hypoechoic / hyperechoic / peripancreatic fluid / irregular and blurred conours / Wirsung dilatation (abve 1mm) / calcification / cyst / inhomogenous structure / fatty tissue infiltration / edematous pancreas / enlarged pancreas / hypodenz / hyperdenz / peripancreatic necrosis / pancreas necrosis / WON / no data

* **Ascites:** yes / no / no data
* **Modified CTSI score:**
* **Abdominal US:** yes / no / no data

if yes: description:……………………….

* **Abdominal X-ray:** yes / no / no data

if yes: description:……………………….

* **Chest X-ray:** yes / no / no data

if yes: description:……………………….

* **Chest CT:** yes / no / no data

if yes: description:……………………….

* **Abdominal CT:** yes / no / no data

if yes: description:……………………….

* **MRCP:** yes / no / no data

if yes: description:……………………….

* **EUS:** yes / no / no data

if yes: description:……………………….

if yes: EUS controlled needle biopsy: yes / no / no data

**9. Therapy**

**Plasmapheresis:** yes / no

* **Number of cycles of plasmapheresis:….**
* Details 1.:
	+ Beginning of plasmapheresis
	+ End of plasmapheresis
	+ The amount of exchanged single blood volume (ml):………
* Details 2.:
	+ Beginning of plasmapheresis
	+ End of plasmapheresis
	+ The amount of exchanged single blood volume (ml):………
* Details 3.:
	+ Beginning of plasmapheresis
	+ End of plasmapheresis
	+ The amount of exchanged single blood volume (ml):………

**Insulin/heparin therapy**

* **Insulin:** yes / no

if yes(details can be added multiple times):

when: 00:00 / 01:00 / 02:00 / 03:00 / 04:00 / 05:00 / 06:00 / 07:00 / 08:00 / 09:00 / 10:00 / 11:00 / 12:00 / 13:00 / 14:00 / 15:00 / 16:00 / 17:00 / 18:00 / 19:00 / 20:00 / 21:00 / 22:00 / 23:00 / 24:00

dose:

unit:

if fluid, concentration:

method of administration:

* **Blood glucose level:** yes / no

if yes (details can be added multiple times):

when: 00:00 / 01:00 / 02:00 / 03:00 / 04:00 / 05:00 / 06:00 / 07:00 / 08:00 / 09:00 / 10:00 / 11:00 / 12:00 / 13:00 / 14:00 / 15:00 / 16:00 / 17:00 / 18:00 / 19:00 / 20:00 / 21:00 / 22:00 / 23:00 / 24:00

value (mmol/l):………

* **Additional glucose/dextrose:** yes / no

if yes (details can be added multiple times):

when: 00:00 / 01:00 / 02:00 / 03:00 / 04:00 / 05:00 / 06:00 / 07:00 / 08:00 / 09:00 / 10:00 / 11:00 / 12:00 / 13:00 / 14:00 / 15:00 / 16:00 / 17:00 / 18:00 / 19:00 / 20:00 / 21:00 / 22:00 / 23:00 / 24:00

type: dextrose / glucose

amount (ml):………

* **Heparin:** yes / no

if yes:

daily dose:

unit:

if fluid, concentration:

method of administration:

**Fluid therapy:** yes / no

if yes (details can be added multiple times):

**when**: 00:00 / 01:00 / 02:00 / 03:00 / 04:00 / 05:00 / 06:00 / 07:00 / 08:00 / 09:00 / 10:00 / 11:00 / 12:00 / 13:00 / 14:00 / 15:00 / 16:00 / 17:00 / 18:00 / 19:00 / 20:00 / 21:00 / 22:00 / 23:00 / 24:00

**typ**e **of fluid:** Isolyte / Ringer lactate / Sterofundin

**amount** (ml):………

**Total** **amount** (ml):…….

**Other therapies**

* **Pain management:** yes / no / no data

if yes:

name:………..……………..active substance:…………..……………dose(gram,milligram, etc.)……………… if fluid, concentration (e.g. 10%, 1g/2ml, etc.)…................... how many times per day (e.g. 3) type of administration:………………………………………………..other notes: ………………………………………

* **Antibiotic therapy:** yes / no / no data

if yes:

name:………..……………..active substance:…………..……………dose(gram,milligram, etc.)……………… if fluid, concentration (e.g. 10%, 1g/2ml, etc.)…................... how many times per day (e.g. 3) type of administration:………………………………………………..other notes: ………………………………………

* **Anticoagulation:** yes / no / no data

if yes:

name:………..……………..active substance:…………..……………dose(gram,milligram, etc.)……………… if fluid, concentration (e.g. 10%, 1g/2ml, etc.)…................... how many times per day (e.g. 3) type of administration:………………………………………………..other notes: ………………………………………

* **Albumin:** yes / no / no data

if yes: dose (ml):…………….

* **Intensive care:** yes / no / no data

if yes: respiratory support / vasopressor therapy / kidney treatment / other

if other: specify:………………….

notes:………………………………..

* **Therapy complication:** Hypokalemia / Hypocalcemiaa / Immunglobulin depletion / Coagulation factor depletion / Hypocalcemia / Metabolic alkalosis / Paresthesia / Nausea / Vomiting / Chest pain / Hypotension / Tetany / Arrhythmias / Infection / Pain / Nerve damage / Thrombosis / Dissecting hematoma / Perforation / Air embolism / AV fistula / other:………....
* **Feeding type:** per os / naso-gastric / naso-jejunal / parenteral / PEG / other
* **Notes:……**

**10. Randomization**

The patient will be randomized by an internet randomization module in the following 3 groups:

**A**. plasmapheresis

**B**. insulin and heparin treatment

**C**. no additional specific treatment

RANDOMIZATION DATE AND TIME:

YEAR: ……………… MONTH: ……………. DAY: ……………… HOUR …………………. MIN: ……………………………………

 **11. Characteristics of the current episode**

**CLOSING DATE AND TIME:**

YEAR: ……………… MONTH: ……………. DAY: ……………… HOUR …………………. MIN: ……………………………………

**EPICRISIS**:……………………………………………………………………………………………………………………………………………

**FINAL REPORT FILE UPLOAD**

**COMPLICATIONS**

* **Pancreatic**: yes / no

if yes: fluid collections / pseudocyst / necrosis / WON

* **Organ** **failure**: yes / no

if yes: lung / heart / kidney

* **Mortality**: yes / no

if yes: exact date and time of death:……………….

Did it happen because of a pancreatic complication? yes / no / no data

* **Comments:………………………………………………**
* **Severity**: mild / moderately severe / severe