Supplementary material

Dosing of Extracorporeal Cytokine Removal In Septic Shock (DECRISS): protocol of a prospective, randomized, adaptive, multicenter clinical trial

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## Schedule of enrolment, interventions and assessments

| STUDY PERIOD | Enrolment | Allocation | Post-allocation** | Follow-up visit/call | Close-out |
|--------------|-----------|------------|-------------------|----------------------|-----------|
| TIMEPOINT    | 6-24 h*   | 0          | 6 h               | 12 h                 | 24 h      |
|              |           |            | 24 h              | 36 h                 | 48 h      |
|              |           |            |                   | X h.                 | 120 h     |
|              |           |            |                   |                      | 28 +/- 7  |
|              |           |            |                   |                      | days      |
|              |           |            |                   |                      | 90 +/- 7  |
|              |           |            |                   |                      | days      |

### ENROLMENT:
- Eligibility screen
  - X
- Informed consent
  - X
- Laboratory test
  - X
- Advanced hemodynamic monitoring***
  - X
- Allocation
  - X

### INTERVENTIONS:
- **Group A**: standard medical therapy (SMT)

### Group B: continuous CytoSorb treatment
- (changed in every 12 hours) + SMT

### Group C: continuous CytoSorb treatment
Supplementary Table 1. Schedule of enrolment, interventions and assessments according to the SPIRIT 2013 statement.

| (changed in every 24 hours)+SMT |   |   |   |   |   |   |
|-------------------------------|---|---|---|---|---|---|
| **ASSESSMENTS:**              |   |   |   |   |   |   |
| Laboratory measurements       | X | X | X | X | X | X |
| SOFA score assessment****     | X | X | X | X | X | X |
| APACHE II score assessment    | X |   |   |   |   |   |
| Follow-up form                | X | X |   |   |   |   |

* after the onset of vasopressor need and after all standard therapeutic measures have been implemented without clinical improvement

** patients’ data will be recorded at T₀, T₆, T₁₂, T₂₄ and then daily until the end of the study period (Tₑ) that is until 12 hours after shock reversal or up to a maximum of 5 days or until the patient’s death, whichever occurs first

*** including global hemodynamic parameters and measures of organ perfusion such as urine output, serum lactate levels, ScvO₂

**** assessed daily
Adverse events

**Serious adverse events** (European regulation on medical devices 2017/745, article 2, (58)):

„Any adverse event that led to any of the following:

- Death,
- Serious deterioration in the health of the subject that resulted in any of the following:
  - Life-threatening illness or injury,
  - Permanent impairment of a body structure or a body function,
  - Hospitalization or prolongation of patient hospitalization,
  - Medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function,
  - Chronic disease”

**Adverse events potentially related to CytoSorb treatment:**

- Allergic reaction to device materials
- Blood loss
- Coagulation within the extracorporeal circuit
- Death
- Decreased platelet count
- Decreased white blood cell count
- Leakage of the circuit or device
- Haemolysis
- Heparin-induced thrombocytopenia
- Hypothermia and chills
- Infection
- Reduction in proteins (total protein, albumin)
- Removal of hormones and drugs
Case report form

Patient personal details:
Insurance number: ........................................
Name: .....................................................
Date of birth: ...........................................
Contact number: ........................................
Gender: Female / Male
Group: ...................................................
Date of ICU care: .................................
Date of inclusion: .................................
Date of treatment start (t₀): ...............
Date of shock reversal: .........................
Date of treatment discontinuation: .........
Date of treatment restart: .................
Date of stopping the treatment (non-responder):
..........................................................
Date of the end of study period (Te): ........

The study period ended 12 hours after shock reversal/with the patient’s death/5 days after randomization

Diagnosis: .............................................
Age: ....... years
Height: ....... cm
Weight: ....... kg
Outcome of ICU care: alive/deceased
ICU care days: ................................. days
Outcome of hospital care: alive/deceased
Hospital care days: ................................. days
Need for invasive ventilation: ...................... days
Need for vasopressor: ............................. days
Need for dialysis: ................................. days
Adverse events: yes/no
Remarks: ..........................................................

Country:
City:
Hospital:
Doctor:
**APACHE II score**: worst values of the previous 24 hours (each box has to be filled on admission after enrolment)  
www.clinicalcalc.com

| Score | %  | Age: years | GCS: |
|-------|----|-----------|------|
| Body temperature: °C |    |           |      |
| MAP: mmHg |    |           |      |
| HR: min⁻¹ |    |           |      |
| Respiratory rate: min⁻¹ |    |           |      |
| FiO₂: % |    |           |      |
| PaO₂: mmHg |    |           |      |
| Arterial pH: |    |           |      |
| Sodium: mEq/L |    |           |      |
| Potassium: mEq/L |    |           |      |
| Creatinine: mg/dl or μmol/l |    |           |      |
| Acute kidney failure: yes / no |    |           |      |
| Hematocrit: % |    |           |      |
| WBC: x10⁹/L |    | organ failure | immunosuppression |

**SOFA score**: worst values of the previous 24 hours (each box has to be filled)  
www.clinicalcalc.com

| t₀ time | t₂₄ time | t₄₈ time | t₇₂ time | t₉₆ time | t₁₂₀ time |
|---------|----------|----------|----------|----------|-----------|
| Score   | %        | Score    | %        | Score    | %        | Score    | %        | Score    | %        |
| FiO₂: % |          | FiO₂: %  |          | FiO₂: %  |          | FiO₂: %  |          | FiO₂: %  |          |
| PaO₂: mmHg |     | PaO₂: mmHg |     | PaO₂: mmHg |     | PaO₂: mmHg |     |
| Mechanical ventilation: yes/no | | Mechanical ventilation: yes/no | | Mechanical ventilation: yes/no | | Mechanical ventilation: yes/no | |
| Thrombocytes: x10⁹/mm³ | | Thrombocytes: x10⁹/mm³ | | Thrombocytes: x10⁹/mm³ | | Thrombocytes: x10⁹/mm³ | |
| Bilirubin: mg/dl v μmol/l | | Bilirubin: mg/dl v μmol/l | | Bilirubin: mg/dl v μmol/l | | Bilirubin: mg/dl v μmol/l | |
| GCS: | | GCS: | | GCS: | | GCS: | |
| MAP: mmHg | | MAP: mmHg | | MAP: mmHg | | MAP: mmHg | |
| Vasopressor: yes/no | | Vasopressor: yes/no | | Vasopressor: yes/no | | Vasopressor: yes/no | |
| Creatinine: mg/dl or μmol/l | Creatinine: mg/dl or μmol/l | Creatinine: mg/dl or μmol/l | Creatinine: mg/dl or μmol/l | Creatinine: mg/dl or μmol/l | Creatinine: mg/dl or μmol/l |
|---------------------------|---------------------------|---------------------------|---------------------------|---------------------------|---------------------------|
| Diuresis: ml/day          | Diuresis: ml/day          | Diuresis: ml/day          | Diuresis: ml/day          | Diuresis: ml/day          |
| <200 / 200-500 / >500    | <200 / 200-500 / >500    | <200 / 200-500 / >500    | <200 / 200-500 / >500    | <200 / 200-500 / >500    |

**Haemodynamics**: (PiCCO Pulsion monitor)

|                                | t₀   | t₆    | t₁₂   | t₂₄   | t₄₈   | t₇₂   | t₉₆   | t₁₂₀  |
|--------------------------------|------|-------|-------|-------|-------|-------|-------|-------|
| Blood pressure (sys/dia)       |      |       |       |       |       |       |       |       |
| MAP (mm Hg)                    |      |       |       |       |       |       |       |       |
| HR (bpm)                       |      |       |       |       |       |       |       |       |
| CVP (mm Hg)                    |      |       |       |       |       |       |       |       |
| Body temperature (°C)          |      |       |       |       |       |       |       |       |
| CI (L/min/m²)                  |      |       |       |       |       |       |       |       |
| SVI (ml/m²)                    |      |       |       |       |       |       |       |       |
| GEDI (ml/m²)                   |      |       |       |       |       |       |       |       |
| SVV (%)                        |      |       |       |       |       |       |       |       |
| PPV (%)                        |      |       |       |       |       |       |       |       |
| SVRI (dyn*sec*cm⁻⁵*m⁻²)        |      |       |       |       |       |       |       |       |
| GEF (%)                        |      |       |       |       |       |       |       |       |
| dPmax (dP/dT)                  |      |       |       |       |       |       |       |       |
| CFI (/min)                     |      |       |       |       |       |       |       |       |
| ELWI (ml/ttkg)                 |      |       |       |       |       |       |       |       |
| PVPI                           |      |       |       |       |       |       |       |       |
| Dobutamine (ug/kg/min)         |      |       |       |       |       |       |       |       |
| Dopamine (ug/kg/min)           |      |       |       |       |       |       |       |       |
|                | t₀   | t₆   | t₁₂  | t₂₄  | t₄₈  | t₇₂  | t₉₆  | t₁₂₀ |
|----------------|------|------|------|------|------|------|------|------|
| Arterenol (ug/kg/min) |      |      |      |      |      |      |      |      |
| Adrenalin (ug/kg/min)    |      |      |      |      |      |      |      |      |
| Vasopressine (ml/min)   |      |      |      |      |      |      |      |      |

**Ventilation and blood gas:** (please note that arterial and central venous blood gas samples should be obtained at the same time)

|                          | t₀ | t₆ | t₁₂ | t₂₄ | t₄₈ | t₇₂ | t₉₆ | t₁₂₀ |
|--------------------------|----|----|-----|-----|-----|-----|-----|------|
| Mode of mechanical ventilation |        |    |      |      |      |      |      |      |
| FiO₂ (%)             |    |    |      |      |      |      |      |      |
| ΔPsupp (cmH₂O)         |    |    |      |      |      |      |      |      |
| PEEP (cmH₂O)          |    |    |      |      |      |      |      |      |
| Vte (ml)              |    |    |      |      |      |      |      |      |
| RR (/min)             |    |    |      |      |      |      |      |      |
| Compl (ml/cmH₂O)       |    |    |      |      |      |      |      |      |
| Resistance (cmH₂O/l/s) |    |    |      |      |      |      |      |      |
| EtCO₂ (mm Hg)         |    |    |      |      |      |      |      |      |
| Ppeak (cmH₂O)         |    |    |      |      |      |      |      |      |
| Pmean (cmH₂O)         |    |    |      |      |      |      |      |      |
| Vds (ml)              |    |    |      |      |      |      |      |      |
| Vds/Vte (%)           |    |    |      |      |      |      |      |      |
| a pH                  |    |    |      |      |      |      |      |      |
| PaCO₂ (mm Hg)         |    |    |      |      |      |      |      |      |
| PaO₂ (mm Hg)          |    |    |      |      |      |      |      |      |
| a BE (mmol/l)         |    |    |      |      |      |      |      |      |
| a HCO₃(mmol/l)        |    |    |      |      |      |      |      |      |
| SaO₂ %                |    |    |      |      |      |      |      |      |
| Glucose (mmol/l) | Sodium (mmol/l) | Potassium (mmol/l) | a Lac (mmol/l) | a Hb (g/dl) | cv pH | PcvCO₂ (mm Hg) | PcvO₂ (mm Hg) | cv BE (mmol/l) |
|-----------------|-----------------|-------------------|----------------|-------------|-------|---------------|---------------|---------------|

**Laboratory parameters:**

|                              | t₀  | t₆  | t₁₂ | t₂₄ | t₄₈ | t₇₂ | t₉₆ | t₁₂₀ |
|------------------------------|-----|-----|-----|-----|-----|-----|-----|-----|
| Red blood cell count (T/l)   |     |     |     |     |     |     |     |     |
| Hematocrit (%)               |     |     |     |     |     |     |     |     |
| Hemoglobin (g/l)             |     |     |     |     |     |     |     |     |
| White blood cell count (G/l) |     |     |     |     |     |     |     |     |
| Neutrophil granulocyte (%)   |     |     |     |     |     |     |     |     |
| Eosinophil granulocyte (%)   |     |     |     |     |     |     |     |     |
| Basophil granulocyte (%)     |     |     |     |     |     |     |     |     |
| Monocyte (%)                 |     |     |     |     |     |     |     |     |
| Lymphocyte (%)               |     |     |     |     |     |     |     |     |
| Platelets (G/l)              |     |     |     |     |     |     |     |     |
| Creatinine (μmol/l) | eGFR (ml/min/tf) | Bilirubin (μmol/l) | GOT (U/l) | GPT (U/l) | Total Protein (g/l) | Albumin (g/l) |
|---------------------|------------------|--------------------|-----------|-----------|--------------------|---------------|

**Fluid balance:**

|                         | t0 | t6 | t12 | t24 | t48 | t72 | t96 | t120 |
|-------------------------|----|----|-----|-----|-----|-----|-----|------|
| Hourly diuresis (ml/h)  |    |    |     |     |     |     |     |      |
| Total urine volume (ml) |    |    |     |     |     |     |     |      |
| Furosemide              |    |    |     |     |     |     |     |      |
| Total fluid intake (ml) |    |    |     |     |     |     |     |      |
| Cristalloid (ml)        |    |    |     |     |     |     |     |      |
| Colloid (ml)            |    |    |     |     |     |     |     |      |
| Transfusion – packed RBC (Unit) |     |     |     |     |     |     |     |      |
| Fresh Frozen Plasma (Unit) |    |    |     |     |     |     |     |      |
| Fluid balance (ml)      |    |    |     |     |     |     |     |      |

**Inflammatory markers** (blood samples for those from the following that can not be measured on site should be frozen for later determination):

|                     | t0 | t6 | t12 | t24 | t48 | t72 | t96 | t120 |
|---------------------|----|----|-----|-----|-----|-----|-----|------|
| PCT (ng/ml)         |    |    |     |     |     |     |     |      |
| CRP (mg/l) | IL-1 (pg/l) | IL-1ra (pg/l) | IL-6 (pg/l) | IL-8 (pg/l) | IL-10 (pg/l) | TNF-α (pg/l) |
|------------|-------------|--------------|-------------|-------------|--------------|--------------|

**KDIGO**

| t0 | t24 | t48 | t72 | t96 | t120 |
|-----|-----|-----|-----|-----|------|
| score | | | | | | |

| stage | Serum creatinine | Urine output |
|-------|------------------|--------------|
| 1     | 1.5–1.9 times baseline OR ≥0.3 mg/dl (≥26.5 mmol/l) increase | <0.5 ml/kg/h for 6–12 hours |
| 2     | 2.0–2.9 times baseline | <0.5 ml/kg/h for ≥12 hours |
| 3     | 3.0 times baseline OR Increase in serum creatinine to ≥4.0 mg/dl (≥353.6 mmol/l) OR Initiation of renal replacement therapy OR, In patients <18 years, decrease in eGFR to <35 ml/min per 1.73 m² | <0.3 ml/kg/h for ≥24 hours OR Anuria for ≥12 hours |

**Indication of antibiotic therapy:**

| Suspected infection | t0 | t24 | t48 | t72 | t96 | t120 |
|---------------------|----|-----|-----|-----|-----|------|
| yes/no Source of infection: | yes/no | yes/no | yes/no | yes/no | yes/no | yes/no |

| Body temperature (<36°C; >38°C) | t0 | t24 | t48 | t72 | t96 | t120 |
|---------------------------------|----|-----|-----|-----|-----|------|
| yes/no                          | yes/no | yes/no | yes/no | yes/no | yes/no | yes/no |
| White blood cell count (<4,000; >12,000) | yes/no | yes/no | yes/no | yes/no | yes/no | yes/no |
|------------------------------------------|--------|--------|--------|--------|--------|--------|
| Gas exchange deterioration               | yes/no | yes/no | yes/no | yes/no | yes/no | yes/no |
| Acute altered consciousness             | yes/no | yes/no | yes/no | yes/no | yes/no | yes/no |
| Haemodynamic instability (circulation support) | yes/no | yes/no | yes/no | yes/no | yes/no | yes/no |
| PCT elevated absolute value (>0,5 ng/ml)  | yes/no | yes/no | yes/no | yes/no | yes/no | yes/no |
| PCT increase within the preceding 24 hours | yes/no | yes/no | yes/no | yes/no | yes/no | yes/no |

**Microbiology:**

| Positive microbiology (yes/no) | t0  | t24 | t48  | t72  | t96  | t120 |
|--------------------------------|-----|-----|------|------|------|------|
| Pathogen(s) identified          |     |     |      |      |      |      |
| Antibiotic therapy (drug name)   |     |     |      |      |      |      |
| Empirical antibiotics were adequate? | yes/no | yes/no | yes/no | yes/no | yes/no | yes/no |
INFORMED CONSENT FORM

Dosing of Extracorporeal Cytokine Removal In Septic Shock:

DECRISS TRIAL

Informed Consent Form for patients over 18 years

Principle Investigator: Prof. Dr. Zsolt Molnár
Name of Organization: the trial is designed and coordinated by the Centre for Translational Medicine at the Medical School of University of Pécs
Name of Project: Dosing of Extracorporeal Cytokine Removal In Septic Shock (DECRISS): a prospective, randomized, adaptive, multicenter clinical trial

This Informed Consent Form has two parts:
• Information Sheet (to share information about the study with you)
• Certificate of Consent (for signatures if you choose to participate)

You will be given a copy of the full Informed Consent Form

Part I: Information Sheet

Introduction
Dear Patient!

Please read thoroughly through the following information and, if you agree, we ask you to undergo the below detailed intervention to support our research efforts. With our trial we can improve the care of patients with septic shock and obtain more information about the pathophysiology of the disease. In case you do not want to participate in the research, we respect your decision of course and your decision will not result in any penalty, loss of benefits or change of treatment.

Purpose of the research
Sepsis and septic shock have mortality rates between 20-50%. In sepsis, the immune response becomes dysregulated which leads to an imbalance between pro-, and anti-inflammatory mediators. When standard therapeutic measures fail to improve patients’ condition, additional therapeutic alternatives are applied to reduce morbidity and mortality. One of the most recent alternatives is extracorporeal cytokine adsorption with a device called CytoSorb (CytoSorbents® Corporation, New Jersey, USA) that has become available in clinical practice in 2011. It is a cytokine adsorbent (binds inflammatory molecules), containing specially developed polymer beads with a large adsorption. Despite promising results in clinical practice, several questions need to be clarified.
before recommendations can be made, including the timing and the length of a single treatment and the overall duration of the therapy

**Aim of the study**

This study aims to compare the efficacy of standard medical therapy and continuous extracorporeal cytokine removal with CytoSorb therapy in patients with early refractory septic shock. Furthermore, we compare the dosing of CytoSorb adsorber device changed every 12 or 24 hours.

**Type of Research Intervention**

Patients eligible for the study in terms of the inclusion and exclusion criteria, will be randomly assigned to one of the three study groups after informed consent. In case the patient is unable to give consent, informed consent will be obtained from the next of kin or his/her legal guardian, information on the study and the treatment will be provided by the attending physician. Patients in Group A will be treated with standard medical therapy (SMT). Patients in Group B will be treated with continuous CytoSorb therapy in addition to standard medical therapy; CytoSorb device will be changed every 12 hours. Patients in Group C will also be treated with continuous CytoSorb therapy in addition to standard treatment, however CytoSorb device will be changed every 24 hours. In each group, the treatment will be continued for a minimum of 24 hours, after that until shock reversal occurs, for a maximum of 5 days or if the patient is deceased.

**Participant Selection**

You were diagnosed with septic shock by your health care providers, and you can be potentially involved in the DECRISS study. The participation of the patient is voluntary and anonymous, the consent may be withdrawn at any time either verbally or in writing. The withdrawal of consent will not result in any penalty or loss of benefits and data will not be used. The patient may contact the coordinator of the research and ask questions at any time.

**Procedures**

Patients eligible for the study in terms of the inclusion and exclusion criteria will be randomly assigned to one of the three study groups – by a computer-generated random number sequence – after informed consent. Overall, 135 patients (1:1:1) will be enrolled (45 in each study arm) to the study.

All patients will receive standard monitoring and care according to the centers’ local standard protocols based on international guideline. It includes 5-lead ECG, pulse oximetry, continuous invasive blood pressure monitoring, central venous cannulation and advanced hemodynamic monitoring. Patients in both Group B and C will receive a haemodialysis catheter inserted into a central vein (femoral, subclavian or internal jugular, as appropriate).

In short, CytoSorb will be placed in a blood pump circuit using a renal replacement device - and according to the current standards recommended by the manufacturers - intravenous anticoagulation will be performed. The attending physician will regularly assess the patient and based on the results, the treatment will be continued or terminated. If the study’s primary endpoint i.e. shock reversal has
been achieved and remains so after finishing 12 hours, CytoSorb therapy will not be continued. However, the treatment can be restarted within 12 hours in case of worsening organ function which is considered by the attending physician as a result of a new onset of hyperinflammatory response. It is expected that there will be patients who do not respond to CytoSorb treatment. Therefore, patients whose clinical condition deteriorates during and within the first 24 hours of CytoSorb therapy will be considered as non-responders and CytoSorb will not be continued.

Blood samples will be collected at the start of the treatment, then 6, 12, 24 hours later, and then daily and in the case, it is required based on the patient’s actual condition. Patients’ data will be recorded on electronic case report forms. Follow-up visits/calls are scheduled on day 28±7 and day 90±7 after the start of the treatment. Adverse events will be collected from the start of the intervention period until follow-up.

The trial will start in 3 centres: University of Pécs, Pécs, Hungary, Hospital Emden, Emden, Germany and Poznan University of Medical Sciences, Poznan, Poland.

**Duration**

The study starts after randomization. In the CytoSorb groups (Group B and Group C), measurements, blood sampling and other recordings are performed immediately after the start of CytoSorb therapy. The study period ends 12 hours after shock reversal or maximum on day 5 after randomization, whichever happens first. The patients will be followed up on day 28±7 and day 90±7 after randomization.

**Risks**

Standard medical therapy includes the insertion of a central venous line and arterial cannulation as well. These procedures are necessary to perform an appropriate intensive clinical care and to cure the patients. Complications and risks associated with arterial cannulation are: allergic reaction to local anesthetic agents, hematoma formation, local and catheter-related infection, nerve damage, arterial thrombosis. In case of central venous line: allergic reaction to local anesthetic agents, hematoma formation, pneumothorax (accumulation of air in the pleural cavity), hemothorax (accumulation of blood in the pleural cavity), catheter-induced thrombosis, local and catheter-related infection. In the intensive care unit, monitoring of the patients can reduce these risks, and if an adverse event occurs, the treatment could start immediately. In case of potential damage, The Patient Rights Representative of the University of Pécs can provide assistance in matters arising during normal patient care.

**Ethical committee providing ethical opinion/approval necessary for the launch of the research:**

Ethics approval was obtained from the Scientific and Research Ethics Committee of the Hungarian Medical Research Council (OGYÉI/65049/2020).

**Withdrawal of consent to participate**
If you wish to withdraw your consent to participate, you may do so at any time during the investigation, orally or in writing, without giving any reason. There is no disadvantage to you from this. You may decide at any time that you no longer wish to participate in the clinical trial. However, the examining doctor may suspend your participation for the benefit of your health or if you find that you are not complying with the requirements of the test plan. If you decide to withdraw from the study, this will not affect your further treatment. You have the right to withdraw from the investigation without giving any explanation. Any questions you may have about the test will be answered by your doctors during the test.

Data collection, handling and access to personal data

If you voluntarily and without any influence decide that you wish to participate in the study, by signing the Certificate of Consent, you also consent to the disclosure of certain personal and health data (date of birth, gender, health or disease data, laboratory, imaging (ultrasound, CT) and physical examinations, eg blood pressure, heart rate, etc.) should be known to the doctors of the examination, the staff involved and the independent ethics committees.

Pursuant to the Hungarian laws, this data is used only for the conduct and scientific analysis of the study.

Only medical/health care staff should have access to the study documentation. All your data will be kept confidential. When you are included in the study, you will be given a code number. The code number and personal data are stored in separate locations. The code number assigned to you in the study will be kept secretly by your doctor in a way and place inaccessible to unauthorized persons for the period prescribed by law. The data is processed anonymously. The data collected in the study is handled by the University of Pécs. The data protection officer of the university is Dr. László Gergely Szőke, e-mail: adatvedelem@pte.hu, Tel.: (72) 501 599/23321 extension. The university's health data protection officer is Dr. Erzsébet Románcz, e-mail: romancz.erzsebet@pte.hu, Tel.: (72) 533 133/33018 extension. The data controller uses an additional data processor for the electronic storage of the data and the transmission of data in compliance with the rules of the GDPR under the conditions specified in the contract: Digital Kft., 6723 Szeged, Csongrádi sgt. 83. Represented by: József Fenyvesi Jr., e-mail: if.fenyvesij@digital.co.hu. You can file a complaint about data processing with the data protection supervisory authority, or you can go to court in case of violation of your data processing rights. In Hungary, the data protection supervisory authority is the National Data Protection and Freedom of Information Authority (1125 Budapest, Szilágyi Erzsébet fásor 22 / C; telephone contact: 06-1-391-1400, e-mail: ugyfelszolgalat@naih.hu, website: www.naih.hu).

Benefits

Your participation is likely to help us find out more about septic shock and provide more information on the use of CytoSorb therapy. There is no expense cover or any allowance for participating in the research.

Sharing the Results

Results will be submitted for publication in a peer-reviewed journal.
Who to Contact

If you have any questions about the study, please feel free to contact your doctor. In the future, if you want to know the progress of the research project, please contact Prof. Dr. Zsolt Molnár (Tel: +36 72/536-246/31547, zsoltmolna@gmail.com) or your doctor.

Part II: Certificate of Consent

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions I have been asked have been answered to my satisfaction. I consent voluntarily to be a participant in this study. I understand the purpose of this trial (ethical approval number: OGYÉI/65049/2020). I do not have further questions for now. I give my consent to participate in this study. I give my consent to use my data for scientific purposes and to release them in publications without mentioning my name. Furthermore, I give my consent to store my data at the place of the research during the time of the research, until its withdrawal or at least 30 years after acquiring data.

At the time of signing, I received a copy of the consent form and summary information.

Print Name of Participant__________________
Signature of Participant __________________
Date __________________________

Day/month/year

If illiterate ¹

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness___________
Signature of witness _____________
Date __________________________

Day/month/year

¹ A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate should include their thumbprint as well.
Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that the following will be done:

1.

2.

3.

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this ICF has been provided to the participant.

Print Name of Researcher/person taking the consent________________________

Signature of Researcher /person taking the consent__________________________

Date ___________________________ Day/month/year