Trial Description

Title

Danger Response in Polytraumatized Patients

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

A large, multi-center biobank with samples from polytraumatized patients to study the post-traumatic danger and immune response will be established. In traumatized patients immune dysregulations frequently result in infectious complications, sepsis, organ failure, regenerative disturbances and mortality. The aim of the study is to characterize this immunology dysregulation and correlate the same to clinical outcomes. In the present study traumatized patients as well as healthy volunteers will be included. The expected data will provide new optimized therapeutic strategies for traumatized patients. The study is one of the key projects from the German Network "Trauma Research" (Netzwerk Traumaforschung, NTF).

Brief Summary in Scientific Language

In this large, multi-center biobank samples from polytraumatized patients to study the post-traumatic danger and immune response will be obtained. As controls healthy volunteers will be included.
Based on the data the following questions should be Adresse:
1. How does trauma modulate the production and release of danger molecules, mediators, coagulation factors and other defined biomarker?
2. How does the injury pattern/severity change the post-traumatic (immune) response and regeneration? Specific data on tissue, cellular and molecular base in a time-course are expected.
3. How do organ function parameters as well as immune monitoring predict the clinical outcomes?
We expect following:
1. To characterize the concentration and kinetics of mediators and danger molecules as well as biomarkers after trauma.
2. To determine the correlations and associations between these molecules with the specific injury pattern/severity and clinical outcomes.
3. To provide new knowledge on molecular and cellular mechanisms of the post-traumatic immune response.
4. To generate new pathophysiologically relevant hypothesis in order to provide improvements in the treatment of traumatized patients.

Do you plan to share individual participant data with other researchers?

Do you plan to share individual participant data with other researchers?

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00017212**
- Date of Registration in DRKS: **2019/05/22**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **94/19 , Ethikkommission des Fachbereichs Humanmedizin der Johann-Wolfgang-Goethe-Universität Frankfurt am Main**

Secondary IDs

Health condition or Problem studied

- ICD10: **V99 - Unspecified transport accident**
- ICD10: **S00 - Superficial injury of head**
- ICD10: **S06 - Intracranial injury**
- ICD10: **S01 - Open wound of head**
- ICD10: **S02 - Fracture of skull and facial bones**
- ICD10: **S03 - Dislocation, sprain and strain of joints and ligaments of head**
- ICD10: **S07 - Crushing injury of head**
- ICD10: **S09 - Other and unspecified injuries of head**
- ICD10: **R04 - Haemorrhage from respiratory passages**
- ICD10: **R02 - Gangrene, not elsewhere classified**
- ICD10: **J96 - Respiratory failure, not elsewhere classified**
- ICD10: **R09 - Other symptoms and signs involving the circulatory and respiratory systems**
- ICD10: **D65 - Disseminated intravascular coagulation [defibrination syndrome]**
-

ICD10: **I26 - Pulmonary embolism**

- ICD10: **S26 - Injury of heart**
- ICD10: **I50 - Heart failure**
- ICD10: **I60 - Subarachnoid haemorrhage**
- ICD10: **I61 - Intracerebral haemorrhage**
- ICD10: **R57 - Shock, not elsewhere classified**
- ICD10: **I97 - Postprocedural disorders of circulatory system, not elsewhere classified**
- ICD10: **A41 - Other sepsis**
- ICD10: **J80 - Adult respiratory distress syndrome**
- ICD10: **N17 - Acute renal failure**
- ICD10: **K72 - Hepatic failure, not elsewhere classified**
- ICD10: **S20 - Superficial injury of thorax**
- ICD10: **S30 - Superficial injury of abdomen, lower back and pelvis**
- ICD10: **S40 - Superficial injury of shoulder and upper arm**
- ICD10: **S50 - Superficial injury of forearm**
- ICD10: **T20 - Burn and corrosion of head and neck**
- ICD10: **T90 - Sequelae of injuries of head**
- ICD10: **T91 - Sequelae of injuries of neck and trunk**
- ICD10: **T92 - Sequelae of injuries of upper limb**
- ICD10: **T93 - Sequelae of injuries of lower limb**
- ICD10: **T94 - Sequelae of injuries involving multiple and unspecified body regions**
- ICD10: **T95 - Sequelae of burns, corrosions and frostbite**
- ICD10: **T98 - Sequelae of other and unspecified effects of external causes**
- ICD10: **T68 - Hypothermia**
- ICD10: **T79 - Certain early complications of trauma, not elsewhere classified**
- ICD10: **T80 - Complications following infusion, transfusion and therapeutic injection**
- ICD10: **T88 - Other complications of surgical and medical care, not elsewhere classified**
- ICD10: **T81 - Complications of procedures, not elsewhere classified**
- ICD10: **T82 - Complications of cardiac and vascular prosthetic devices, implants and grafts**
- ICD10: **T83 - Complications of genitourinary prosthetic devices, implants and grafts**

- ICD10: **T84 - Complications of internal orthopaedic prosthetic devices, implants and grafts**
- ICD10: **T85 - Complications of other internal prosthetic devices, implants and grafts**
- ICD10: **T89 - [---]***
- ICD10: **S23 - Dislocation, sprain and strain of joints and ligaments of thorax**
- ICD10: **S24 - Injury of nerves and spinal cord at thorax level**
- ICD10: **S25 - Injury of blood vessels of thorax**
- ICD10: **S26 - Injury of heart**
- ICD10: **S27 - Injury of other and unspecified intrathoracic organs**
- ICD10: **S28 - Crushing injury of thorax and traumatic amputation of part of thorax**
- ICD10: **S29 - Other and unspecified injuries of thorax**

Interventions/Observational Groups

- Arm 1: **Group 1: Healthy volunteers**

  In both groups blood sampling will be performed. There are no planned special other interventions.
  Group 1 is the reference group, and blood will be taken only once.

  The following research questions should be answered:

  1. How does trauma modulate the release of danger molecules, mediators, coagulation factors and other defined biomarkers?
  2. How does the injury pattern change the post traumatic response and regeneration on organ, cellular and molecular basis during the time course?
  3. What predictive power regarding the clinical outcomes do the analyzed factors have?

- Arm 2: **Group 2: polytraumatized patients**

  Group 2 included severely injured trauma patients and blood will be taken at the following time points:
  1, 8, 24, 48 h and 5, 10 days after trauma.

  The following research questions should be answered:

  1. How does trauma modulate the release of danger molecules, mediators, coagulation factors and other defined biomarkers?
  2. How does the injury pattern change the post traumatic response and regeneration on organ, cellular and molecular basis during the time course?
  3. What predictive power regarding the clinical outcomes do the analyzed factors have?

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Other**
- Allocation: **Other**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Other**
- Purpose: **Other**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

- cytokie-/chemokine profiles
- coagulation factors
- complement factors
- cell damage and function marker
- DAMPs and PAMPs
- cell s
- organ functions
- diagnoses
- duration of the stay at the intensive care unit and hospital
- organ failure, mortality

Secondary Outcome

- mediators
- stem cells
- cell marker
- protein/gene expressions
- differential blood analysis
- infections
- SIRS
- sepsis
- shock
- organ dysfunctions
- injury
- regenerative disturbances
- complications
- mortality
- transfusion
- perioperative complications

Countries of recruitment

- DE **Germany**
- CH **Switzerland**

Locations of Recruitment

- Medical Center **Frankfurt a.M.**
- Medical Center **Aachen**
- Medical Center **Ulm**
- Medical Center **Leipzig**
- Medical Center **Berlin**
- Medical Center **Erlangen**
- Medical Center **Zürich**
- Medical Center **Köln**

Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2019/06/01**
- Target Sample Size: **6000**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **International**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

- (Poly)trauma with an ISS ≥ 16
- preclinical time < 120 min
- regular termination of the "shock room" phase
- informed consent

Exclusion criteria

- patients younger then 18
- death within 24 hours post trauma
- ISS < 16
- kardiopulmonal reanimation
- gravidity
- patients who underwent immunosuppressive or chemotherapy within the last three months

- Immune suppressive therapy
- HIV, hepatitis A, B, C, HCV, CMV
- kidney dialysis

Addresses

■ **Primary Sponsor**

Klinik für Unfall-, Hand- und WiederherstellungschirurgieUniversitätsklinikum Frankfurt der Goethe Universität
60590 Frankfurt
Germany

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

■ **Contact for Scientific Queries**

Klinik für Unfall-, Hand- und WiederherstellungschirurgieKlinik der Goethe-Universität
Ms. Prof. Dr. phil. nat. Borna Relja
Theodor-Stern-Kai 7
60590 Frankfurt
Germany

Telephone: **0049-69-6301-84372**
Fax: **0049-69-6301-84375**
E-mail: **info at bornarelja.com**
URL: **http://www.kgu.de/index.php?id=126**

■ **Contact for Public Queries**

Klinik für Unfall-, Hand- undWiederherstellungschirurgieKlinik der Goethe-Universität
Ms. Dr. Marlene Bellen
Theodor-Stern-Kai 7
60590 Frankfurt
Germany

Telephone: **0049-68-6301-6189**
Fax: **[---]***
E-mail: **marlene.bellen at kgu.de**
URL: **[---]***

Sources of Monetary or Material Support

■ **Private sponsorship (foundations, study societies, etc.)**

Private sponsorship (foundations, study societies, etc.)

Deutsche Gesellschaft für Unfallchirurgie e.V. (DGU)
10623 Berlin
Germany

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

- **Institutional budget, no external funding (budget of sponsor/PI)**

Klinik für Unfall-, Hand- und WiederherstellungschirurgieKlinik der Goethe-Universität Frankfurt
Theodor-Stern-Kai 7
D-60590
Germany

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

Status

- Recruitment Status: **Recruiting planned**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

** This entry means the parameter is not applicable or has not been set.*

**** This entry means that data is not displayed due to insufficient data privacy clearing.*