

**PLEASE NOTE:** *This trial has been registered retrospectively.*

## Trial Description

### Title

**Acute versus chronic inflammation: analysis of the T-cell function in the tonsilla palatina as surrogate marker of the immune status with patients with peritonsillar abscess versus patients with chronic tonsillitis**

### Trial Acronym

**HTTS**

### URL of the trial

[---]\*

### Brief Summary in Lay Language

**The main purpose of the study is to investigate the immune status of patients with severe local infection or chronic inflammation in tissue from tonsils, as easily available secondary lymphoid organ.**

**The background of the study is to investigate the T cell function of these patients in order to distinguish and identify of immunological processes caused by acute systemic inflammatory reactions versus chronic local inflammatory reactions. There are examined tonsils of patients with chronic tonsillitis as well as of patients with peritonsillar abscess. As controls serve tonsils taken from patients with rhonchopathy.**

**Potential study participants are patients in whom the tonsils are routinely removed due to chronic or acute inflammation or due to rhonchopathy.**

**Patient recruiting has already begun within the primary study "Systemic versus local inflammation: Analysis of tonsillar T-cell function as a surrogate marker of the immune status in sepsis versus chronic tonsillitis" (DRKS 00005313); however, due to recruiting problems of sepsis patients the study was early terminated and the study design was changed.**

### Brief Summary in Scientific Language

**The main purpose of the study is to investigate the functional characteristics of T cells in tonsils of patients with 1) severe local inflammatory reaction (peritonsillar abscess) to sepsis, 2) chronic tonsillitis and 3) hypertrophy of tonsils (rhonchopathy) to identify differences in the immune reaction caused by antigen stimulation in lymphatic tissue between 1) acute and partly systemic versus 2) chronic and local inflammation and 3) control T-lymphocytes. We expect that the analysis of the T-cell function of these 3 groups let us find out important parameters and characteristics for the differentiation and identification of immunological processes caused by acute systemic inflammation reactions versus chronic local inflammation reactions. Furthermore, we will try to investigate the possibility of using tonsils (as the only secondary lymphatic organ) for the analysis and diagnosis of the immunological status of patients concerned.**

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

[---]\*

### Description IPD sharing plan

[---]\*

## Organizational Data

- DRKS-ID: **DRKS00007801**
- Date of Registration in DRKS: **2015/02/27**
- 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.: **3972-01/14 , Ethikkommission der Friedrich-Schiller-Universität Jena an der Medizinischen Fakultät**

## Secondary IDs

## Health condition or Problem studied

- ICD10: **J36 - Peritonsillar abscess**
- ICD10: **J35.0 - Chronic tonsillitis**
- ICD10: **J35.1 - Hypertrophy of tonsils**

## Interventions/Observational Groups

- Arm 1: **Patient with peritonsillar abscess and emergent tonsillectomy; taking of tissue samples of palatine tonsils**
- Arm 2: **Patients with chronic tonsillitis and scheduled resection of palatine tonsils; taking of tissue samples of palatine tonsils**
- Arm 3: **Patients with rhonchopathy due to tonsil hypertrophy and scheduled resection of palatine tonsils; taking of tissue samples of palatine tonsils**

## Characteristics

- Study Type: **Non-interventional**



Study Type: **Non-interventional**

- Study Type Non-Interventional: **Other**
- Allocation: **Non-randomized controlled trial**
- Blinding: [---]\*
- Who is blinded: [---]\*
- Control: **Other**
- Purpose: **Basic research/physiological study**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

### Primary Outcome

**Difference in the T cell response of patients with peritonsillar abscess, chronic tonsillitis and tonsil hyperplasia regarding activation, proliferation and apoptosis and thereby investigate the existence of T cell specific parameters to systemic and local inflammation**

### Secondary Outcome

**Investigation of the use of the tonsils, as an easily available secondary lymphoid organ, for the determination of the immune status of patients with severe local inflammatory reaction to sepsis**

### Countries of recruitment

- DE **Germany**

### Locations of Recruitment

- Medical Center **HNO und andere Kliniken, Jena**

### Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2014/01/24**
- Target Sample Size: **21**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

### Inclusion Criteria

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

### Additional Inclusion Criteria

**All patient groups:**

- 1. male or female patients, age at least 18 years**
- 2. written informed consent**

**Only patient group A:**

**patients with peritonsillar abscess and emergent tonsillectomy**

**Only patient group B:**

**patients with chronic tonsillitis (with 3 or more episodes of recidival acute tonsillitides per year) and scheduled for routine tonsillectomy**

**Only patient group C:**

**patients without acute or chronic tonsillitis, but scheduled for routine tonsilectomy due to rhonchopathy or obstructive sleep apnea syndrome**

### Exclusion criteria

- 1. therapy with steroids or other immunosuppressive therapy**
- 2. severe chronic diseases in medical history**
- 3. Therapy with coagulation inhibitors or abnormally low coagulation status**

### Addresses

■ **Primary Sponsor**

**Integriertes Forschungs- und Behandlungszentrum Sepsis und  
SepsisfolgenKlinik und Poliklinik für Hals-, Nasen- und Ohrenheilkunde  
Mr. Prof. Dr. Orlando Guntinas-Lichius  
Erlanger Allee 101  
07747 Jena  
Germany**

Telephone: **03641-9-35127**

Fax: **03641-9-35129**

E-mail: **orlando.guntinas at med.uni-jena.de**

URL: **www.cscs.uniklinikum-jena.de**

■ **Contact for Scientific Queries**

**Integriertes Forschungs- und Behandlungszentrum Sepsis und  
SepsisfolgenKlinik und Poliklinik für Hals-, Nasen- und Ohrenheilkunde  
Mr. Prof. Dr. Orlando Guntinas-Lichius**

### **Contact for Scientific Queries**

**Integriertes Forschungs- und Behandlungszentrum Sepsis und  
SepsisfolgenKlinik und Poliklinik für Hals-, Nasen- und Ohrenheilkunde  
Mr. Prof. Dr. Orlando Guntinas-Lichius**

**Erlanger Allee 101**

**07747 Jena**

**Germany**

Telephone: **03641-9-35127**

Fax: **03641-9-15129**

E-mail: **orlando.guntinas at med.uni-jena.de**

URL: **www.csccl.uniklinikum-jena.de**

#### ■ **Contact for Public Queries**

**Integriertes Forschungs- und Behandlungszentrum Sepsis und  
SepsisfolgenKlinik und Poliklinik für Hals-, Nasen- und Ohrenheilkunde  
Mr. Prof. Dr. Orlando Guntinas-Lichius**

**Erlanger Allee 101**

**07747 Jena**

**Germany**

Telephone: **03641-9-35127**

Fax: **03641-9-35129**

E-mail: **orlando.guntinas at med.uni-jena.de**

URL: **www.csccl.uniklinikum-jena.de**

#### ■ **Collaborator, Other Address**

**Klinik und Poliklinik für Hals-, Nasen- und Ohrenheilkunde Universitätsklinikum  
Jena**

**Lessingstraße 2**

**07743 Jena**

**Germany**

Telephone: [---]\*

Fax: [---]\*

E-mail: [---]\*

URL: [---]\*

## **Sources of Monetary or Material Support**

- **Public funding institutions financed by tax money/Government funding body  
(German Research Foundation (DFG), Federal Ministry of Education and  
Research (BMBF), etc.)**

**Center for Sepsis Control and Care (CSCC)**

**Erlanger Allee 101**

**07747 Jena**

**Germany**



**Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)**

**Center for Sepsis Control and Care (CSCC)  
Erlanger Allee 101  
07747 Jena  
Germany**

Telephone: **03641-9-323374**

Fax: **03641-9-323379**

E-mail: **csc at med.uni-jena.de**

URL: **www.csc.uniklinikum-jena.de**

## Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2014/09/30**

## Trial Publications, Results and other documents

- Paper [---]\*

\* 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.