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

Trial Description

Title

Epididymo-orchitis: Etiology, Inflammation, Impact on Fertility, and Clinical Course

Trial Acronym

Giessen Epididymitis Study

URL of the trial

[---]*

Brief Summary in Lay Language

The study deals with a combined inflammation of the testicle and the epididymis. The causes for the disease and the causative factors, the inflammation and whether it thereby affecting the ability to breed there will be research. Study participants may be male persons who are older than 18 years and present with an acute inflammation of the epididymis. The study includes a detailes medical history inlcuding questionnaires, a clinical investigation, and the investigation of urine, blood and semen at first presentation and subsequent visits on days 14 and 84. Afterwards a continuous follow-up is performed by telephone or personal presentation of the patient.

Brief Summary in Scientific Language

The study deals with the Epididymoorchitis. Should be investigated, the etiology, inflammation, the effects on fertility and the clinical course. Study participants are male, older than 18 and have an acute epididymitis.

Organizational Data

- DRKS-ID: **DRKS00003325**
- Date of Registration in DRKS: **2011/11/10**
- 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.: **100/07 , Ethik-Kommission des Fachbereichs Medizin der Justus-Liebig-Universität Gießen**

Secondary IDs

Health condition or Problem studied

- ICD10: **N45 - Orchitis and epididymitis**
- Free text: **acute epididymitis**

Interventions/Observational Groups

- Arm 1: **Therapy according to the guidelines**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Epidemiological study**
- Allocation: **Single arm study**
- Blinding: **Open (masking not used)**
- Who is blinded: **[---]***
- Control: **Uncontrolled/Single arm**
- Purpose: **Other**
- Assignment: **Single (group)**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

• investigate the etiology of acute epididymo-orchitis (bacterial and viral investigation of urine, p.r.n. blood, semen, testicular and epididymal tissue)

Secondary Outcome

• determine the pathogen in correspondence to sexual activity/age (IIEF-questionnaire)
• determine systemic inflammatory parameters (CRP, White blood cell count, procalcitonin, cytokines)
• Documentation of markers for testicular cancer (AFP, HCG, LDH)
• determine the impact on seminal parameters and sperm (semen analysis according to WHO 1999 and WHO 2010)
• determine inflammatory parameters in the male genitourinary tract (2 resp. 4-glas test, leukocytes in urine, PSA in blood, inflammatory parameters in sement: leukocytes, elastase, cytokines)
• determine the impact on fertility (semen analysis and future paternity)

- **determine comorbidities associated with acute epididymo-orchitis (anamnesis, clinical investigation, laboratory parameters, medical reports)**
- **determine the impact of analgetic and antimicrobial premedication on the clinical course (documentation of type and duration of premedication)**
- **determine the impact of previous antimicrobial therapy on the etiology**
- **determine the interval between onset of symptoms and seeking medical help**
- **determine ultrasonographic features associated with acute epididymo-orchitis**
- **(testicular size, epididymal size, perfusion oft he spermatic cord, testis and epididymis, concomitant hydrocele, abscess formation).**
- **determine a possible side-specific distribution**
- **determine urinary flow parameters and bladder function (uroflowmetry, residual urine, urodynamic bladder investigation, IPSS questionnaire)**
- **determine the impact of the infection on quality of life using questionnaires (NIH-CPSI, CESI)**
- **determine the need for surgical intervention**
- **determine risk factors to suffer epididymo-orchitis**
- **determine percentage of patients with epididymitis and epididymo-orchitis (clinical and ultrasound assessment)**
- **determine the clinical course (ambulatory visits, follow-up by telephone)**
- **determine the benefit of 16 S rRNA gene sequencing**
- **determine the possibility of recurrent and the development of chronic epididymo-orchitis**

Countries of recruitment

- DE **Germany**

Locations of Recruitment

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2007/07/16**
- Target Sample Size: **250**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Male**
- Minimum Age: **18 Years**

Gender: **Male**

Minimum Age: **18 Years**

- Maximum Age: **no maximum age**

Additional Inclusion Criteria

- Male, at least 18 years of age
- Suffer acute epididymitis, defined as a) enlarged epididymis and b) epididymal hypervascularity in ultrasonography

Exclusion criteria

- Testicular torsion
- Other primary scrotal diseases than epididymo-orchitis
- Any condition that, in the opinion of the investigator, would comprise the study

NOTE: Subjects may be enrolled in this study regardless of whether previous antimicrobial therapy was initiated.

Addresses

- **Primary Sponsor**

Klinik und Poliklinik für Urologie, Kinderurologie und Andrologie
Universitätsklinikum Gießen und Marburg GmbH, Standort Gießen
Mr. Dr. med. Adrian Pilatz
Rudolf-Buchheim-Str. 7
35392 Gießen
Germany

Telephone: **0641/985-56362**
Fax: **0641/985-44519**
E-mail: **adrian.pilatz at chiru.med.uni-giessen.de**
URL: **http://www.uniklinikum-giessen.de**

- **Contact for Scientific Queries**

Klinik und Poliklinik für Urologie, Kinderurologie und Andrologie
Universitätsklinikum Gießen und Marburg GmbH, Standort Gießen
Mr. Dr. med. Adrian Pilatz
Rudolf-Buchheim-Str. 7
35392 Gießen
Germany

Telephone: **0641/985-56362**
Fax: **0641/985-44519**

Contact for Scientific Queries

Klinik und Poliklinik für Urologie, Kinderurologie und Andrologie
Universitätsklinikum Gießen und Marburg GmbH, Standort Gießen
Mr. Dr. med. Adrian Pilatz
Rudolf-Buchheim-Str. 7
35392 Gießen
Germany

Telephone: **0641/985-56362**
Fax: **0641/985-44519**
E-mail: **adrian.pilatz at chiru.med.uni-giessen.de**
URL: **http://www.uniklinikum-giessen.de**

- **Contact for Public Queries**

Klinik und Poliklinik für Urologie, Kinderurologie und Andrologie
Universitätsklinikum Gießen und Marburg GmbH, Standort Gießen
Mr. Dr. med. Adrian Pilatz
Rudolf-Buchheim-Str. 7
35392 Gießen
Germany

Telephone: **0641/985-56362**
Fax: **0641/985-44519**
E-mail: **adrian.pilatz at chiru.med.uni-giessen.de**
URL: **http://www.uniklinikum-giessen.de**

Sources of Monetary or Material Support

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

Justus Liebig Universität
Klinik und Poliklinik für Urologie, Kinderurologie und Andrologie
Mr. Dr. med. Adrian Pilatz
Rudolf-Buchcheim-Str.7
35392 Gießen
Germany

Telephone: **+49-641-985-56362**
Fax: **+49-641-985-44519**
E-mail: **adrian.pilatz at chiru.med.uni-giessen.de**
URL: **[---]***

Status

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

Trial Publications, Results and other documents

Please note:
There are additional attributes available concerning this trial. To open an extended view please click here.