



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

Trial Description

Title

A retrospective clinical follow-up analysis of 32 patients with bilomas

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

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Brief Summary in Scientific Language

Biloma are defined collections of bile fluids. Owing to the infrequency of this disease, studies addressing bilomas are rare. We aim to analyze etiology, clinical presentation, spectrum of pathogens, multiresistance patterns, therapy Options, and resolution rate of bilomas.

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

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00015208**
- Date of Registration in DRKS: **2018/08/06**
- 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.: **108/17 S , Ethik-Kommission der Fakultät für Medizin der Technischen Universität München**



Secondary IDs

Health condition or Problem studied

- ICD10: **K83 - Other diseases of biliary tract**

Interventions/Observational Groups

- Arm 1: **No groups, clinical follow-up with spectrum of pathogens, therapies and outcome of patients with biloma treated in the Klinikum rechts der Isar between 2004 and 2015.**

Characteristics

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

Primary Outcome

Aim of this study is to describe symptoms, therapie options and outcome of bilomas

Secondary Outcome

/

Countries of recruitment

- **DE Germany**

Locations of Recruitment

- University Medical Center **Klinikum rechts der Isar, München**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2017/04/04**
- Target Sample Size: **32**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **110 Years**

Additional Inclusion Criteria

- **Presentation of a bile fluid collection after injection of contrast agent into the biliary system via ERC/PTCD**
 - **Typical medical history like ERC, TACE, hepatobiliary surgery, photodynamic therapy or liver transplantation.**
- Retrospective inclusion of patients with biloma treated between 2004 to 2015 in the Klinikum rechts der Isar**

Exclusion criteria

Incomplete patient records

Addresses

- **Primary Sponsor**
Klinikum rechts der Isar, TU München
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■ **Contact for Scientific Queries**

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Sources of Monetary or Material Support

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

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Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2018/01/01**

Trial Publications, Results and other documents

- Trial results **A retrospective clinical and microbial analysis of 32 patients with bilomas.**

* 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.