Trial Description

Title

Prospectiv, single-center trial to evaluate the rate of of hypoxaemia and hypotension in patients undergoing endoscopic retrograde cholangiopancreatography (ERCP) with sedation.

Trial Acronym

DoubleHypoERCP

URL of the trial

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Brief Summary in Lay Language

Endoscopic retrograde cholangiopancreatography (ERCP) is an uncomfortable therapeutic procedure using an endoscope with a light source and a video camera. additionally, X rays were used to visualize patients bile and pancreatic ducts. This procedure cannot be performed without adequate sedation. Every sedation have the risks of serious cardio-respiratory complications such as lack of oxygen (hypoxaemia) and low blood pressure (hypotension).
At the moment it is not clear if sedation preformed by anaesthesia personal has an benefit for saftey of the sedative technique, patient satisfaction and examiner statisfaction in patients undergoing ERCP procedures

Brief Summary in Scientific Language

The aim of this observational trial is to evaluate the rate of of hypoxaemia and hypotension and the rate of successful ERCP in patients undergoing endoscopic retrograde cholangiopancreatography (ERCP).
Also the failure to complete the procedure due to sedation-related problems, satisfaction of the patient, satisfaction of the examiner, willingness to repeat the procedure in the same conditions, rate of intubation of papille vateri,heart rate, BIS-Index, endtidale CO2, rate of successful ERCP, duration of ERCP, cumulated dose of propofol, cumulated dose of remifentanil, recovery time and the mortality (30 days) will be recorded.

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

[---]*

Description IPD sharing plan

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Organizational Data

- DRKS-ID: **DRKS00005201**
- Date of Registration in DRKS: **2014/02/19**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **no**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **S-457/2013 , Ethik-Kommission I der Medizinischen Fakultät Heidelberg**

Secondary IDs

Health condition or Problem studied

- ICD10: **K83.0 - Cholangitis**
- ICD10: **K76.9 - Liver disease, unspecified**

Interventions/Observational Groups

- Arm 1: **Detection of sedation relateted complication if sedation administreded by anaesthesia personal in patients undergoing ERCP procedure.**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Single arm study**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Uncontrolled/Single arm**
- Purpose: **Other**
- Assignment: **Single (group)**
- Phase: **N/A**

Study Type: **Interventional**

Study Type Non-Interventional: **[---]***

Allocation: **Single arm study**

Blinding: **[---]***

Who is blinded: **[---]***

Control: **Uncontrolled/Single arm**

Purpose: **Other**

Assignment: **Single (group)**

Phase: **N/A**

- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Rate of hypoxaemia (oxygen saturation lower than 90%) and hypotension (bloodpressure lower than 90 mmHg) during sedation.
Oxygen saturation will be measured continously and blood pressure will be measured every five minutes.

Secondary Outcome

Failure to complete the procedure due to sedation-related problems documented at Case Fall Report (CFR)
satisfaction of patient: Likert-scale after the examination bevor leaving the recovery area
satisfaction of examine Likert-scale after the examination
willingness to repeat procedure in the same conditions after the examination bevor leaving the recovery area,
rate of intubation of papille vateri documented at Case Fall Report (CFR) during the examination
heart rate documented every 5 minutes at Case Fall Report (CFR) during the examination
BIS-Index documented every 5 minutes at Case Fall Report (CFR) after the examination
endtidale CO2 documented every 5 minutes at Case Fall Report (CFR) after the examination
rate of successful ERCP documented at CFR after the examination
duration of ERCP documented in minutes at CFR
after the examination
cumulated dose of propofol documented at CFR
after the examination
cumulated dose of remifentanil documented at CFR after the examination
recovery time documented at CFR bevor leaving the recovery area
mortality (30 days)
documentes at seperate sheet

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Interdisziplinäres Endoskopie Zentrum, Heidelberg**

Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2014/03/04**
- Target Sample Size: **200**
- 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

Age: 18 years and older, patients undergoing endoscopic retrograde cholangiopancreatography

Exclusion criteria

**impaired mental state or language problem,
patients with known allergy to propofol and/ or remifentanyl, need of general anaesthesia,
pregnancy, oxygen saturation lower than 90% befor interventation, bloodpressure lower than 90 mmHg bevor intervention**

Addresses

- **Primary Sponsor**

  Interdisziplinäres Endoskopie ZentrumUniklinikum Heidelberg
  Im Neuenheimer Feld 410
  69120 Heidelberg
  Germany

Primary Sponsor

Interdisziplinäres Endoskopie ZentrumUniklinikum Heidelberg
Im Neuenheimer Feld 410
69120 Heidelberg
Germany

Telephone: **06221/56-8713**
Fax: **06221/56-8904**
E-mail: **[---]***
URL: **[---]***

■ **Contact for Scientific Queries**

Klinik für AnästhesiologieUniklinik Heidelberg
Ms. Dr.med Nicole Ganion
Im Neuenheimer Feld 110
69120 Heidelberg
Germany

Telephone: **06221/56-36154**
Fax: **06221/56-5345**
E-mail: **Nicole.Ganion at med.uni-heidelberg.de**
URL: **[---]***

■ **Contact for Public Queries**

Klinik für AnästhesiologieUniklinik Heidelberg
Ms. Dr.med Nicole Ganion
Im Neuenheimer Feld 110
69120 Heidelberg
Germany

Telephone: **06221/56-36154**
Fax: **06221/56-5345**
E-mail: **Nicole.Ganion at med.uni-heidelberg.de**
URL: **[---]***

■ **Collaborator, Other Address**

Interdisdziplinäres Endoskopie ZentrumUniversitätsklinik Heidelberg
Ms. Dr.med. Anja Schaible
Im Neuenheimer Feld 410
69120 Heidelberg
Germany

Telephone: **06221/56-6128**
Fax: **06221/56-6148**
E-mail: **anja.schaible at med.uni-heidelberg.de**

Collaborator, Other Address

Interdisdziplinäres Endoskopie ZentrumUniversitätsklinik Heidelberg
Ms. Dr.med. Anja Schaible
Im Neuenheimer Feld 410
69120 Heidelberg
Germany

Telephone: **06221/56-6128**
Fax: **06221/56-6148**
E-mail: **anja.schaible at med.uni-heidelberg.de**
URL: **[---]***

Sources of Monetary or Material Support

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

Interdisziplinäres Endoskopie ZentrumUniklinikum Heidelberg
Im Neuenheimer Feld 410
69120 Heidelberg
Germany

Telephone: **06221/56-8713**
Fax: **06221/56-8904**
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.*