



Trial Description

Title

Prospective registration of patients with duodenal adenomas: endoscopic therapy, complications and duration of remission

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

Duodenal adenomas are the majority of the benign tumors of the upper small intestine. Although they are classified as benign, they have the potential of malignant transformation. In most cases duodenal adenomas are asymptomatic. Concerning the therapy of the duodenal adenomas there is no standard procedure. The consensus is to remove the duodenal adenoma endoscopically because of its chance of malignant transformation. The complication rate increases with the size of the adenoma. That is why surgery is done in extreme large adenomas. Overall there is very few data on the therapy and its complications. Hence, we want to follow up on all our patients with duodenal adenomas (size, description of the adenoma, therapeutic procedure, process) to learn more about the adenomas and assess the advancement of the therapeutic management.

Brief Summary in Scientific Language

Duodenal adenomas are the majority of the benign tumors of the upper small intestine. Although they are classified as benign, they have the potential of malignant transformation. They mostly occur sporadically or in cases of FAP. Concerning the therapy of the duodenal adenomas there is no standard procedure. The consensus is to remove the duodenal adenoma endoscopically because of its chance of malignant transformation. The complication rate increases with the size of the adenoma. Overall there is very few data on the therapy and its complications. Primary target of the study is to clarify the complication rate of endoscopic therapy of duodenal adenomas and to determine which complications occur how often. Secondary criteria are to investigate: a) influence of the complication rate by the type of the adenoma (size, location, histology, pattern) as well as b) type and handling of the endoscopic maneuver (resection en bloc-piece meal-APC-therapy). Furthermore the duration till the complete remission and the duration of the remission itself are of interest.

Organizational Data

■ DRKS-ID: **DRKS00003081**



DRKS-ID: **DRKS00003081**

- Date of Registration in DRKS: **2011/05/11**
- 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.: **FF 29/2011 , Ethikkommission der Landesärztekammer Hessen**

Secondary IDs

Health condition or Problem studied

- ICD10: **D13.2 - Benign neoplasm: Duodenum**
- ICD10: **D12.6 - Benign neoplasm: Colon, unspecified**

Interventions/Observational Groups

- Arm 1: **endoscopic resection of the duodenal adenoma with subsequent registration of complications and duration of remission**

Characteristics

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

Primary Outcome

The goal of the study is the systematic registration of patients with duodenal adenomas at the Dr. Horst Schmidt Klinik in Wiesbaden. Primary outcome is to clarify the complication rate for endoscopic therapy of duodenal adenomas and to see which complications occur in which frequency

Secondary Outcome

Secondary outcomes of the study are:

- influence of the complication rate concerning size, location, histology, pattern), type of endoscopic therapy (resection en bloc-piece meal-APC-therapy)
- duration till complete remission and duration of remission

Countries of recruitment

- DE **Germany**

Locations of Recruitment

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2011/05/15**
- Target Sample Size: **100**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **100 Years**

Additional Inclusion Criteria

- **age over 18 years**
- **patients with suspected or diagnosed duodenal adenomas**

Exclusion criteria

- **missing consent**
- **pregnacy**
- **Coagulation disorders (Quick <60%, PTT > 50 s, WBC < 100.000/ml)**

Addresses

■ Primary Sponsor

HSK Wiesbaden
Ms. Prof. Andrea May
Ludwig Erhard Str. 100
65193 Wiesbaden
Germany

Telephone: **0611432420**
Fax: **0611432418**
E-mail: **Andrea.May at hsk-wiesbaden.de**
URL: [---]*

■ Contact for Scientific Queries

HSK Wiesbaden
Ms. Dr. Insa Messer
Ludwig Erhard Str. 100
65199 Wiesbaden
Germany

Telephone: **0611432194**
Fax: **0611432418**
E-mail: **Insa.Messer at hsk-wiesbaden.de**
URL: [---]*

■ Contact for Public Queries

HSK Wiesbaden
Ms. Dr. Insa Messer
Ludwig Erhard Str. 100
65199 Wiesbaden
Germany

Telephone: **0611432194**
Fax: **0611432418**
E-mail: **Insa.Messer at hsk-wiesbaden.de**
URL: [---]*

Sources of Monetary or Material Support

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

HSK Wiesbaden
Mr. Prof. Christian Ell
Ludwig ERhard Str. 100

DRKS-ID: **DRKS00003081**

Date of Registration in DRKS: **2011/05/11**

Date of Registration in Partner Registry or other Primary Registry: [---]*



Deutsches Register
Klinischer Studien

German Clinical
Trials Register

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

HSK Wiesbaden

Mr. Prof. Christian Ell

Ludwig ERhard Str. 100

65199 Wiesbaden

Germany

Telephone: **0611432420**

Fax: **0611432418**

E-mail: **christian.ell at hsk-wiesbaden.de**

URL: [---]*

Status

- Recruitment Status: **Recruiting ongoing**
- 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.