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

Trial Description

Title

Liver pre-conditioning by the portal vein embolization (PVE) before liver resection.

Trial Acronym

Volume

URL of the trial

http://www.charite.de/avt/forschung/workgroup_for_the_liver/ongoing-projects.html

Brief Summary in Lay Language

Nowadays, a partly resection of the liver is the appropriate method in many patients suffering from a tumor of the liver. In such cases, the resection of 70 to 75% of healthy tissue is possible.
If a larger amount of tissue needs to be removed by surgery, or if the liver is already aggrieved by the disease, there is an increase in both of the risks of postoperative (liver-) insufficiency and mortality.
The selective embolization (occlusion) of one of the branches of the portal vein (PVE) before surgery allows the enlargement/growth of the remaining tissue after resection. With PVE, the blood flow in the part of the liver selected for resection is massively decreased.
This leads to „shrinkage" of the embolized segments of the liver, while the non-embolized segments (the remaining part after resection) "grow" in volume simultaneously.
The aim of the Study is a dynamic description of the growth process in the liver after PVE. With the recently developed LiMAx – liver function test and the use of MR-imaging, those processes are monitored in weekly intervals after PVE.
Additional parameters such as the blood flow in the portal vein measured via ultrasound or the serum levels of cytokines and growth hormones are detected and monitored during the whole process of the study.
70 patients with different tumors of the liver are to be included in this study.
Duration for recruitment is 1,5 years, duration of the study is 2 years.

Brief Summary in Scientific Language

Partial hepatectomy is the method of choice to treat many liver tumours e.g. cholangio-, hepatocellular or metastases of the colon carcinoma. In many cases the limiting factor for operation is the remaining (remnant) volume of the liver after resection (future liver remnant, FLR). Dependent on the individual liver function 60 to 80% of the liver volume can be resected safely.
A partial occlusion of the portal vein (portal vein embolization, PVE) enables a "volume shift" from those liver segments to be resected to those which are to remain. Although this method has already been used in high counts worldwide, the mechanisms, the kinetics and the changes in the FRL after embolization are

very vague and have - especially regarding the human organism - not been determined yet.
Regarding animal-models growth processes similar to those after partial hepatectomy have been reported for PVE.
The primary aim of this study is to quantify the dynamic effects of PVE on the liver volume using MR – imaging and a recently developed liver function – Test (LiMAx).
Additional factors which may have an influence on the regeneration of the liver (e.g. portal blood flow or pre-existing defects of the liver tissue) are monitored and analysed.
Proliferation of FRL and degeneration /atrophy of the embolized fraction of the liver tissue are to be correlated with the changing of cytokines and growth factors serum levels.
The goal of this project is to describe the dynamic development of proliferation/atrophy of the liver segments after PVE using volumetric and functional analysis by MRI and LiMAx. In order to minimize postoperative liver insufficiency rate and reduce the risk of preoperative tumor growth the time frame between PVE and liver resection should be optimized.
Duration of the Study is 2 years. 70 Patients obtaining a PVE are analysed prospectively. Using a new liver function test (LiMAx), the liver function is measured before and after PVE in weekly intervals.
In the same intervals volumetric analysis of the liver-segments using MR-imaging, analysis of the portal blood flow using Doppler ultrasound and determination of serum levels of cytokines and growth factors (HGF, TGFß1, TNFα, IL6, GH, IGF1) are performed and correlated with each other.

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

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00003723**
- Date of Registration in DRKS: **2012/05/16**
- 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.: **Antragsnummer: EA1/306/11 , Ethik-Kommission der Charité -Universitätsmedizin Berlin-**

Secondary IDs

Health condition or Problem studied

- ICD10: **C22 - Malignant neoplasm of liver and intrahepatic bile ducts**

Interventions/Observational Groups

- Arm 1: **Patients who become PVE prior to liver resection will be included. Before and after PVE as well as one, two, three and four weeks after PVE and after resection at days 1, 10 and 85 the liver function test (LiMAx) and MRT will be performed. Also cytokines and standard laboratory parameters will be measured at those time points.**

Characteristics

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

Primary Outcome

Volume function analysis at the time points: before and after PVE as well as one, two, three and four weeks after PVE and after resection at days 1, 10 and 85.

Secondary Outcome

[---]*

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Workgroup for the Liver, Charité, Klinik für Allgemein, Visceral and Transplantation Surgery, Berlin**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2012/04/01**
- Target Sample Size: **70**
- 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

1. Patient is a male or female, obtaining a PVE during preoperative conditioning process
2. Patient is over 18 years of age
3. Patient provides written informed consent

Exclusion criteria

1. Patient with a GFR < 30 ml/min/1,73 m2
2. Patient has or requires an implantable electronic defibrillator, pacemaker or other ferromagnetic implants
3. Patient with congenital long-QT-syndrom or corresponding family history
4. Patient has a known allergy to the contrast agent Primovist ®
5. Patient is treated with drugs prolonging the repolarization, e.g. Class III - anti arrhythmic agents (e.g. Amiodaron, Sotalol).
6. Patient has already underwent liver surgery (cholecystectomia is not a reason for exclusion
7. Any factors, decreasing the ability to apply and cooperate during the (e.g. mental dysfunction, claustrophobia or abuse of drugs)
8. Patient is pregnant or lactating

Addresses

- **Primary Sponsor**

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  Augustenburger Platz 1
  13353 Berlin

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Sources of Monetary or Material Support

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

Charité Campus Virchow-Klinikum
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Germany

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

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Germany

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **www.charite.de**

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.*