# L-BLP25 in Patients With Colorectal Carcinoma After Curative Resection of Hepatic Metastases (LICC)

**This study is currently recruiting participants.**
Verified October 2011 by Johannes Gutenberg University Mainz

First Received on October 27, 2011. Last Updated on February 2, 2012 History of Changes

| | |
|---|---|
| **Sponsor:** | Dr. Carl Schimanski |
| **Information provided by (Responsible Party):** | Dr. Carl Schimanski, Johannes Gutenberg University Mainz |
| **ClinicalTrials.gov Identifier:** | NCT01462513 |

## Purpose

Comparative evaluation of recurrence-free survival time between the treatment groups (L-BLP25 plus cyclophosphamide versus placebo vaccination and saline infusion.)

| Condition | Intervention | Phase |
|---|---|---|
| Colon Carcinoma<br>Rectum Carcinoma | Biological: L-BLP25<br>Biological: Placebo | Phase II |

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Efficacy Study
Intervention Model: Parallel Assignment
Masking: Double Blind (Subject, Investigator)
Primary Purpose: Treatment

Official Title: LICC: L-BLP25 in Patients With Colorectal Carcinoma After Curative Resection of Hepatic Metastases - a Randomized, Placebo-controlled, Multicenter, Multinational, Double Blinded Phase II Trial

**Resource links provided by NLM:**

MedlinePlus related topics: Cancer

U.S. FDA Resources

**Further study details as provided by Johannes Gutenberg University Mainz:**

Primary Outcome Measures:

- Comparative evaluation of recurrence-free survival time between the treatment groups (L-BLP25 plus cyclophosphamide versus placebo vaccination and saline infusion) [ Designated as safety issue: No ]

  The primary variable of this trial is recurrence free survival (RFS) time. RFS time will be measured from the date of randomization to the date of recurrence. For subjects not known to have experienced recurrence or death at the time of analysis, the time between the date of randomization and the date of last evaluation for recurrence will be calculated and used as a censored observation in the analysis.

Secondary Outcome Measures:

- Overall survival time [ Designated as safety issue: No ]

  Overall survival (OS) time of all and of of MUC1 positive cancers, respectively, will be measured from the date of randomization to the date of death. For subjects not known to be deceased at the time of analysis, the time between the date of randomization and the date of last contact, or date lost to follow-up, will be calculated and used as a censored observation in the analysis.

- Safety/tolerability [ Designated as safety issue: Yes ]

  Assessment of safety will include:

  - AEs, SAEs
  - Vital signs (body temperature, respiratory rate, heart rate, and blood pressure) and physical examinations,
  - Clinical laboratory assessments from hematology and biochemistry samples

- Recurrence free survival time in a subgroup of MUC1 positive cancers [ Designated as safety issue: No ]

  Recurrence free survival (RFS) time of MUC1 positive cancers will be measured from the date of randomization to the date of relapse based on standard imaging. For subjects not known to have experienced recurrence or death at the time of analysis, the time between the date of randomization and the date of last evaluation for recurrence or death will be calculated and used as a censored observation in the analysis.

- Overall survival time in a subgroup of MUC1 positive cancers [ Designated as safety issue: No ]

  Overall survival (OS) time of MUC1 positive cancers will be measured from the date of randomization to the date of death. For subjects not known to be deceased at the time of analysis, the time between the date of randomization and the date of last contact, or date lost to follow-up, will be calculated and used as a censored observation in the analysis.

| | |
|---|---|
| Estimated Enrollment: | 159 |
| Study Start Date: | August 2011 |
| Estimated Study Completion Date: | September 2017 |
| Estimated Primary Completion Date: | September 2016 (Final data collection date for primary outcome measure) |

| Arms | Assigned Interventions |
|---|---|
| Experimental: L-BLP25<br>L-BLP25 vaccination | Biological: L-BLP25<br>Vaccination 930µg per vaccination once weekly for 8 weeks, then at 6-week intervals during years 1 and 2, at 12-week intervals during year 3<br>Other Name: MUC1-antibody |
| Placebo Comparator: Placebo<br>Placebo | Biological: Placebo<br>Vaccination: Placebo 930µg per vaccination, once weekly for 8 weeks, then at 6-week intervals during years 1 and 2 and at 12-week intervals in year 3 |

**Detailed Description:**
This trial is designed for patients with metastatic colorectal carcinoma (CRC), who have undergone a complete resection of their primary tumor and recent resection of their liver metastases (R0 or R1) with curative intent. No generally accepted standard care is available following curative-intent resection of hepatic metastases in colorectal cancer patients. L-BLP25 is a cancer vaccine that targets MUC1, a well known tumor-associated antigen. Recently, it has been shown that MUC1 is associated with cellular transformation as demonstrated by tumorigenicity and can confer resistance to genotoxic agents. High levels of MUC1 cell surface expression, reported immunosuppressive activities of its released ectodomain, and anti-adhesive properties all contribute to the ability of the MUC1 antigen to protect and promote tumor cell growth and survival, and make MUC1 an attractive target for cancer immunotherapy.

Based on these results, L BLP25 may have potential as adjuvant therapy after curative resection of hepatic metastases in colorectal cancer patients.

## Eligibility

| | |
|---|---|
| Ages Eligible for Study: | 18 Years and older |
| Genders Eligible for Study: | Both |
| Accepts Healthy Volunteers: | No |

**Criteria**

Inclusion Criteria:

- Signed written informed consent.
- Female patients of childbearing potential (and if appropriate male patients with female partners of childbearing potential) must be willing to use an adequate method of contraception for 4 weeks prior to, during and 12 weeks after the last dose of trial medication. A negative pregnancy test is required for female subjects. Adequate contraception for female subjects is defined as two barrier methods, or one barrier method with a spermicide, or intrauterine device or use of hormonal female contraceptive.
- Histologically confirmed diagnosis of adenocarcinoma of the colon or rectum with complete resection of primary tumor and no evidence of local relapse.
- Metastatic disease of the liver, with recent (< 6 weeks prior to randomization) resection (R0 or R1) of all liver metastases. Metastasectomy may have been either synchronous or metachronous. Any neoadjuvant therapy may have been applied for maximal 3 months prior to metastasectomy.
- Subject has had a colonoscopy or rectoscopy within the last three months prior to initiation of therapy
- Subject has an ECOG performance status of 0 or 1.
- Subject has adequate hematologic, hepatic, and renal function within 2 weeks prior to initiation of therapy as defined by the following: Absolute neutrophils > 1,500/mm3 and platelets > 140,000/mm3. Bilirubin < 1.5 x upper limit of normal (ULN). AST and ALT < 2.5 x ULN. Creatinine < 1.5 x ULN. International Normalized Ratio (INR) and partial thromboplastin time (PTT) in the normal range of the local lab.
- Willingness to comply with study protocol requirements.

Exclusion Criteria:

- Metastases other than liver metastases.
- R2 and Rx resected liver metastases. Patients with R1 resected liver metastases can be included if a further surgical resection is seen as not indicated or necessary in the surgeon´s opinion.
- Chemotherapy within 4 weeks prior to randomization.
- Receipt of immunotherapy (e.g. interferons, tumor necrosis factor, interleukins, or growth factors [GM-CSF, G-

CSF, M- CSF], monoclonal antibodies) within 4 weeks (28 days) prior to randomization.

- Any known autoimmune disease, past or current.
- A recognized immunodeficiency disease including cellular immuno-deficiencies, hypogammaglobulinemia or dysgammaglobulinemia; hereditary or congenital immunodeficiencies.
- Known or newly diagnosed active hepatitis B infection and/or hepatitis C infection, autoimmune hepatitis, known human immunodeficiency virus infection, or any other infectious process that in the opinion of the investigator could compromise the subject's ability to mount an immune response, or expose him/ her to likelihood of more and/or severe side effects.
- Past or current history of malignant neoplasm other than CRC, except for curatively treated non-melanoma skin cancer, in-situ carcinoma of the cervix or other cancer curatively treated and with no evidence of disease for at least 5 years.
- Medical or psychiatric conditions that would interfere with ability to provide informed consent, communicate side effects, or comply with protocol requirements.
- Clinically significant cardiac disease, e.g. cardiac failure of New York Heart Association classes III-IV; uncontrolled angina pectoris, uncontrolled arrhythmia, uncontrolled hypertension, myocardial infarction in the previous 12 months as confirmed by an ECG.
- Splenectomy.
- Previous (less than 4 weeks prior to randomization) or concurrent treatment with a non-permitted drug.
- Pregnancy and lactation period.
- Participation in another clinical study within 30 days prior to randomization.
- Known hypersensitivity to the study treatment drugs.
- Known alcohol or drug abuse.
- Legal incapacity or limited legal capacity.
- Any other reason that, in the opinion of the investigator, precludes the subject from participating in this study.

## Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT01462513

### Locations

**Austria**

LKH-Universitätsklinikum Graz — **Not yet recruiting**
Graz, Austria, 8036
Contact: Hellmut Samonigg, Prof. Dr. +4331638513115 hellmut.samonigg@medunigraz.at
Principal Investigator: Hellmut Samonigg, Prof. Dr.
Sub-Investigator: Michael Halm, MD
Sub-Investigator: Martin Pichler, MD
Sub-Investigator: Renate Schaberl-Moser, MD

Salzburger Universitätsklinikum, Universitätsklinik für Innere Medizin III — **Not yet recruiting**
Salzburg, Austria, 5020
Contact: Richard Greil, Prof. Dr. +43 662 4482 2880 r.greil@salk.at
Principal Investigator: Richard Greil, Prof. Dr.
Sub-Investigator: Brigitte Mlineritsch, MD

**Germany**

Campus Virchow-Klinikum, Charite Centrum 8 — **Not yet recruiting**
Berlin, Germany, 13353
Contact: Daniel Seehofer, MD +49 30450552001 daniel.seehofer@charite.de
Principal Investigator: Daniel Seehofer, MD
Sub-Investigator: Roberta Bova, MD
Sub-Investigator: Dennis Eurich, MD
Sub-Investigator: Wladimir Faber, MD
Sub-Investigator: Anja Kießling, MD

Klinikum Dortmund gGmbH, Medizinische Klinik Mitte — **Not yet recruiting**
Dortmund, Germany, 44137
Contact: Michael Heike, Prof. Dr. +49 231 95321770 michael.heike@klinikumdo.de
Principal Investigator: Michael Heike, Prof. Dr.
Sub-Investigator: Sabine Bäumer, MD
Sub-Investigator: Peter Boris Czyborra, MD

Onkologische Gemeinschaftspraxis Dörfel & Göhler — **Not yet recruiting**
Dresden, Germany, 01127
Contact: Steffen Dörfel, Dipl. med. +49 351 849507141 doerfel@onkozentrum.de
Principal Investigator: Steffen Dörfel, Dipl. med.
Sub-Investigator: Thomas Göhler, MD

Universitätsklinikum Essen WTZ-Ambulanz, Innere Medizin (Tumorforschung) — **Recruiting**
Essen, Germany, 45122
Contact: Stefan Kasper, MD +49 201 72385062 stefan.kasper@uk-essen.de
Principal Investigator: Stefan Kasper, MD
Sub-Investigator: Marit Ahrens, MD
Sub-Investigator: Jörg Hense, MD
Sub-Investigator: Mathias Hoiczyl, MD
Sub-Investigator: Johannes Meiler, MD
Sub-Investigator: Mareike Tometten, MD
Sub-Investigator: Martin Schuler, MD

Klinikum der Johann W- Goethe Unversität, Klinik für Allgemein- und Viszeralchirurgie **Not yet recruiting**
Frankfurt, Germany, 60590
Contact: Wolf O Bechstein, Professor +49 69 63015251 wolf.bechstein@kgu.de
Principal Investigator: Wolf O Bechstein, Professor
Sub-Investigator: Christiane Gog, MD
Sub-Investigator: Angelika Mertens, MD
Sub-Investigator: Christiane Mönch, MD
Sub-Investigator: Jörg Trojan, Professor

Onkologische Schwerpunktpraxis Eppendorf **Recruiting**
Hamburg, Germany, 20249
Contact: Susanna Hegewisch-Becker, Prof. Dr. +49 40 4602001 hegewisch@onkologie-eppendorf.de
Principal Investigator: Susanna Hegewisch-Becker, Prof. Dr.
Sub-Investigator: Thorsten Dierlamm, MD

Städtisches Klinikium Abt. Allgemein- und Visceralchirurgie **Recruiting**
Karlsruhe, Germany, 76133
Contact: Michael Schön, Professor +49 721 9742101 michael.schoen@klinikum-karlsruhe.de
Principal Investigator: Michael Schön, Professor
Sub-Investigator: Daniel Gärtner, MD
Sub-Investigator: Monika Harbrecht-Hessle, MD

Universitätsmedizin Mainz **Recruiting**
Mainz, Germany, 55131
Contact: Carl C Schimanski, MD +49 6131 176076 schimanski@1-med.klinik.uni-mainz.de
Contact: Markus Möhler, MD +49 6131 175712 markus.moehler@unimedizin-mainz.de
Principal Investigator: Carl C Schimanski, MD
Sub-Investigator: Tina Friesing-Sosnik, MD
Sub-Investigator: Markus Möhler, MD
Sub-Investigator: Julia Sieg, MD
Sub-Investigator: Daniel Foltys, MD
Sub-Investigator: Marcus A. Wörns, MD
Sub-Investigator: Michael Heise, MD

Praxis für Hämatologie und Onkologie **Recruiting**
Mülheim an der Ruhr, Germany, 45468
Contact: Jan Schröder, PD Dr. med. +49 208 76981 jan.schroeder@onkologie-mh.de
Principal Investigator: Jan Schröder, PD Dr. med.
Sub-Investigator: Katharina Sieg, MD

Klinikum der Universität München-Grosshadern, Medizinische Klinik III **Not yet recruiting**
München, Germany, 81377
Contact: Volker Heinemann, Professor +49 89 70953019 Volker.Heinemann@med.uni-muenchen.de
Principal Investigator: Volker Heinemann, Professor
Sub-Investigator: Roswitha Forstpointer, MD
Sub-Investigator: Clemens Gießen, MD
Sub-Investigator: Dominik Modest, MD
Sub-Investigator: Sebastian Stinzing, MD

GP für Hämatologie und Onkologie Offenburg **Recruiting**
Offenburg, Germany, 77654
Contact: Bernhard Linz, MD +49 781 9705779 linz@onkologie-offenburg.de
Principal Investigator: Bernhard Linz, MD
Sub-Investigator: Andreas Jakob, MD
Sub-Investigator: Marianne Müller, MD

Oncologianova GmbH **Recruiting**
Recklinghausen, Germany, 45657
Contact: Friedrich Overkamp, MD +49 2361 90427 23 overkamp@onkologie-re.de
Principal Investigator: Friedrich Overkamp, MD
Sub-Investigator: Ludger Heflik, MD
Sub-Investigator: Till-Oliver Emde

Leopoldina Krankenhaus **Recruiting**
Schweinfurt, Germany, 97422
Contact: Stephan Kanzler, Prof. Dr. +49 9721 7200 skanzler@leopoldina.de
Principal Investigator: Stephan Kanzler, Prof. Dr.
Sub-Investigator: Hans Reinel, MD
Sub-Investigator: Andrea Buwe

Robert-Bosch Krankenhaus, Zentrum für Innere Medizin **Recruiting**
Stuttgart, Germany, 70376
Contact: Matthias Vöhringer, MD +49 711 81013506 matthias.voehringer@rbk.de
Principal Investigator: Matthias Vöhringer, MD
Sub-Investigator: Walter-Erich Aulitzky, Professor
Sub-Investigator: Liza Bacchus-Gerybadze, MD
Sub-Investigator: Martin Kaufmann, MD
Sub-Investigator: Sonja Martin, MD
Sub-Investigator: Annette Steckkönig, MD

Universitätsklinikum, Zentrum für Innere Medizin **Not yet recruiting**
Ulm, Germany, 89081
Contact: Götz von Wichert, Professor +49 731 50044508 goetz.wichert@uniklinik-ulm.de
Principal Investigator: Götz von Wichert, Professor
Sub-Investigator: Johann Ahn, MD
Sub-Investigator: Angelika Kestler, MD
Sub-Investigator: Jochen Kraus, MD
Sub-Investigator: Sven Walter, MD
Sub-Investigator: Eugen Zizer, MD

Klinikum Weiden, Medizinische Klinik I **Recruiting**
Weiden, Germany, 92637
Contact: Frank Kullmann, Professor +49 961 3033114 frank.kullmann@kliniken-nordoberpfalz.ag
Principal Investigator: Frank Kullmann, Professor
Sub-Investigator: Armin Leitner, MD
Sub-Investigator: Carsten Schwab, MD
Sub-Investigator: Holger Tuchbreiter, MD

**Sponsors and Collaborators**

Dr. Carl Schimanski

**Investigators**

Principal Investigator: Carl Christoph Schimanski, MD Universitätsmedizin Mainz

## More Information

No publications provided

| | |
|---|---|
| Responsible Party: | Dr. Carl Schimanski, Coordinating Investigator, Johannes Gutenberg University Mainz |
| ClinicalTrials.gov Identifier: | NCT01462513 History of Changes |
| Other Study ID Numbers: | LICC01 |
| Study First Received: | October 27, 2011 |
| Last Updated: | February 2, 2012 |
| Health Authority: | Germany: Paul-Ehrlich-Institut; Austria: Federal Office for Safety in Health Care |

Keywords provided by Johannes Gutenberg University Mainz:
Colon carcinoma
Rectum carcinoma
Liver metastases

Additional relevant MeSH terms:

| | |
|---|---|
| Carcinoma | Digestive System Neoplasms |
| Colorectal Neoplasms | Neoplasms by Site |
| Neoplasm Metastasis | Digestive System Diseases |
| Rectal Neoplasms | Gastrointestinal Diseases |
| Liver Neoplasms | Colonic Diseases |
| Colonic Neoplasms | Intestinal Diseases |
| Neoplasms, Glandular and Epithelial | Rectal Diseases |
| Neoplasms by Histologic Type | Neoplastic Processes |
| Neoplasms | Pathologic Processes |
| Intestinal Neoplasms | Liver Diseases |
| Gastrointestinal Neoplasms | |

ClinicalTrials.gov processed this record on February 14, 2012