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

Purpose

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

<table>
<thead>
<tr>
<th>Condition</th>
<th>Intervention</th>
<th>Phase</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colon Carcinoma</td>
<td>Biological: L-BLP25</td>
<td>Phase II</td>
</tr>
<tr>
<td>Rectum Carcinoma</td>
<td>Biological: Placebo</td>
<td></td>
</tr>
</tbody>
</table>

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)

<table>
<thead>
<tr>
<th>Arms</th>
<th>Assigned Interventions</th>
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<tbody>
<tr>
<td>Experimental: L-BLP25</td>
<td>Biological: L-BLP25 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</td>
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<tr>
<td>L-BLP25 vaccination</td>
<td>Other Name: MUC1-antibody</td>
</tr>
<tr>
<td>Placebo Comparator:</td>
<td>Biological: Placebo Vaccination 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</td>
</tr>
<tr>
<td>Placebo</td>
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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.

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

Countries and Locations

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

Locations

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http://clinicaltrials.gov/ct2/show/NCT01462513

17.02.2012
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<thead>
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<th>Institution</th>
<th>Status</th>
<th>City, Country, Zip Code</th>
<th>Contact</th>
<th>Principal Investigator</th>
<th>Sub-Investigators</th>
</tr>
</thead>
<tbody>
<tr>
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</tbody>
</table>

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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

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