Treatment of Chemotherapy Refractory Human Epidermalgrowth Factor Receptor-2(HER-2) Positive Advanced Solid Tumors (CART-HER-2)

This study is currently recruiting participants.

See Contacts and Locations

Verified January 2016 by Han weidong, Chinese PLA General Hospital
Sponsor:
Chinese PLA General Hospital
Information provided by (Responsible Party):
Han weidong, Chinese PLA General Hospital
ClinicalTrials.gov Identifier:
NCT01935843
First received: September 1, 2013
Last updated: January 26, 2016
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History of Changes

Purpose

RATINALE: Placing a tumor antigen chimeric receptor that has been created in the laboratory into patient autologous T cells may make the body build immune response to kill cancer cells.

PURPOSE: This clinical trial is to study genetically engineered lymphocyte therapy in treating patients with HER-2 positive advanced solid tumors,such as breast cancer, gastric cancer, hepatic carcinoma, endometrial cancer and ovary cancer.

Condition	Intervention	Phase

Advanced HER-2 Positive Solid Tumors Chemotherapy Refactory HER-2 Antibody Inhibitor Therapy Refactory	Biological: CART-HER-2	Phase 1 Phase 2

Study Type: Interventional
Study Design: Intervention Model: Single Group Assignment
Masking: None (Open Label)
Primary Purpose: Treatment

Official Title: Clinical Study of Chimeric HER-2 Antigen Receptor-modified T Cells in Chemotherapy Refractory HER-2 Advanced Solid Tumors

Further study details as provided by Han weidong, Chinese PLA General Hospital:

Primary Outcome Measures:

- Occurrence of Study related adverse events [Time Frame: Until week 24]

Secondary Outcome Measures:

- Anti-leukemia response to CART-HER-2 cell infusions [Time Frame: up to 24 weeks]

Other Outcome Measures:

- In vivo existence of CART-HER-2 [Time Frame: 1 year]

Estimated Enrollment: 10
Study Start Date: September 2013
Estimated Study Completion Date: September 2017
Estimated Primary Completion Date: September 2016 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Anti-tumor responses of CART-HER-2	Biological: CART-HER-2

Detailed Description:

PRIMARY OBJECTIVES:

I.Determine the safety and feasibility of the chimeric antigen receptor T cells transduced with anti-HER-2 vector(referred to as CART-HER-2 cells).

II.Determine duration of in vivo survival of CART-HER-2 cells. RT-PCR(reverse transcription polymerase chain reaction)analysis of whole blood will be used to detect and quantify survival of CART-HER-2 TCR zeta:CD137 and TCR(T-cell receptor) zeta cells over time.

SECONDARY OBJECTIVES:

I.For patients with detectable diseases, measure anti-tumor response due to CART-HER-2 cell infusions.

II.Estimate relative trafficking of CART-HER-2 cells in tumor bed.

III.Determine if cellular or humoral host immunity develops against the murine anti-HER-2, and assess correlation with loss of detectable CART-HER-2(loss of engraftment).

IV.Determine the relative subsets of CART-HER-2 T cells (Tcm,Tem,and Treg).

OUTLINE: Patients are assigned to 1 group according to order of enrollment. Patients receive anti-HER-2-CAR (coupled with CD137 and CD3 zeta signalling domains)vector-transduced autologous T cells on days 0,1, and 2 in the absence of unacceptable toxicity.

After completion of study treatment, patients are followed intensively for 6 months, every 3 months for 2 years, and annually thereafter for 13 years.

Estimate relative trafficking of CART-HER-2 cells in peripheral blood.

Eligibility

Ages Eligible for Study:	18 Years to 80 Years (Adult, Senior)
Sexes Eligible for Study:	All
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Chemotherapy refractory HER-2-positive breast cancer, gastric cancer, non-small cell lung cancer, and chemotherapy resistant or relapsed ovary cancer.
- Relapsed patients after anti-HER-2 using antibody or kinase inhibitor therapy.
- Patients must be 18 years of age or older.
- Patients must have an ECOG (Eastern Cooperative Oncology Group)performance status of 0-2.
- Patients must have evidence of adequate bone marrow reserve, hepatic and renal function as evidenced by the following laboratory parameters:

Absolute neutrophil count greater than 1500/mm3. Platelet count greater than 100,000/mm3. Hemoglobin greater than 10g/dl (patients may receive transfusions to meet this parameter).

Total bilirubin < 1.5 times upper limits of normal. Serum creatinine less than or equal to 1.6 mg/ml or the creatinine clearance must be greater than 70 ml/min/1.73m(2).

- Seronegative for HIV antibody.
- Seronegative for active hepatitis B, and seronegative for hepatitis C antibody.
- Patients must be willing to practice birth control during and for four months following treatment.NOTE:women of child-bearing age must have evidence of negative pregnancy test.
- Patients must be willing to sign an informed consent.

Exclusion Criteria:

- Patients with life expectancy less than 12 months will be excluded.
- Patients with uncontrolled hypertension (> 160/95), unstable coronary disease evidenced by uncontrolled arrhythmias, unstable angina, decompensated congestive heart failure (> New York Heart Association Class II), or myocardial infarction within 6 months of study will be excluded.
- Patients with any of the following pulmonary function abnormalities will be excluded: FEV(forced expiratory volume), < 30% predicted; DLCO (diffusing capacity of lung for carbon monoxide) < 30% predicted (post-bronchodilator); Oxygen Saturation less than 90% on room air.
- Patients with severe liver and kidney dysfunction or consciousness disorders will be excluded.
- Pregnant and/or lactating women will be excluded.
- Patients with active infections, including HIV, will be excluded, due to unknown effects of the vaccine on lymphoid precursors.
- Patients with any type of primary immunodeficiencies will be excluded from the study.
- Patients requiring corticosteroids (other than inhaled) will be excluded.
- Patients with history of T cell tumors will be excluded.
- Patients who are participating or participated any other clinical trials in latest 30 days will be excluded.

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT01935843

Contacts

Contact: Weidong Han, Dr. +86-10-13651392893 hanwdrsw@sina.com

Contact: Xiru Li, Dr. +86-10-13910594988 Huyi0401@yahoo.com.cn

Locations

China, Beijing

Chinese PLA General Hospital — Recruiting

Beijing, Beijing, China, 100853

Contact: Weidong Han, Dr. +86-10-13811421950 hanwdrsw@sina.com

Principal Investigator: Yao Wang, Dr.

Principal Investigator: Yao Wang, Dr.

Sponsors and Collaborators

Chinese PLA General Hospital

Investigators

Study Chair: Weidong Han, Dr. Chinese PLA General Hospital

More Information

Responsible Party:	Han weidong, Professor and Director, Chinese PLA General Hospital
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