Efficacy and Safety of Romidepsin CHOP vs CHOP in Patients With Untreated Peripheral T-Cell Lymphoma

This study is currently recruiting participants. (see Contacts and Locations)

Verified September 2015 by The Lymphoma Academic Research Organisation

Sponsor:
The Lymphoma Academic Research Organisation

Information provided by (Responsible Party):
The Lymphoma Academic Research Organisation

ClinicalTrials.gov Identifier:
NCT01796002

First received: January 31, 2013
Last updated: September 4, 2015
Last verified: September 2015
History of Changes

Purpose

Primary objective of the study is to compare the efficacy of romidepsin when administered with CHOP versus CHOP alone in subjects with previously untreated peripheral T-cell lymphoma (PTCL) in terms of progression-free survival (PFS) assessed according to Response criteria for malignant lymphoma 1999 by RAC.

Condition	Intervention	Phase
Peripheral T-cell Lymphoma	Drug: Romidepsin + CHOP Drug: CHOP	Phase 3

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Safety/Efficacy Study
Intervention Model: Parallel Assignment
Masking: Open Label
Primary Purpose: Treatment

Official Title: PHASE 3 MULTI-CENTER RANDOMIZED STUDY TO COMPARE EFFICACY AND SAFETY OF ROMIDEPSIN CHOP (**Ro-CHOP**) VERSUS CHOP IN PATIENTS WITH PREVIOUSLY UNTREATED PERIPHERAL T-CELL LYMPHOMA

Resource links provided by NLM:

MedlinePlus related topics: Lymphoma

Drug Information available for: Romidepsin

Genetic and Rare Diseases Information Center resources: Lymphosarcoma Peripheral T-cell Lymphoma

U.S. FDA Resources

Further study details as provided by The Lymphoma Academic Research Organisation:

Primary Outcome Measures:

- The primary efficacy endpoint is Progression Free Survival (PFS) using the response criteria for malignant lymphoma (1999) by a RAC [Time Frame: 60 months] [Designated as safety issue: No]

Estimated Enrollment: 420
Study Start Date: January 2013

Estimated Study Completion Date: July 2024
Estimated Primary Completion Date: July 2019 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Romidepsin + CHOP Patients in experimental arm receive romidepsin plus CHOP (**Ro-CHOP**) administered in 3 w eek cycles for 6 cycles. Romidepsin is administered at a dose of 12 mg/m² IV on day 1 and day 8 every 3 w eeks.	Drug: Romidepsin + CHOP **Ro-CHOP** administered in 3 w eek cycles for 6 cycles or until progression Romidepsin is administered at a dose of 12 mg/m² IV on day 1 and day 8 every 3 w eeks.
Active Comparator: CHOP Patients in control Arm receive cyclophosphamide, doxorubicin, vincristine and prednisone (CHOP) administered in 3 w eek cycles for 6 cycles.	Drug: CHOP CHOP (cyclophosphamide, doxorubicin, vincristine and prednisone) administered in 3 w eek cycles for 6 cycles.

Eligibility

Ages Eligible for Study: 18 Years to 80 Years
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

1. Males and females of 18 years of age to 80 years of age.
2. Understand and voluntarily sign an informed consent document prior to any study related assessments/procedures are conducted.
3. Able to adhere to the study visit schedule and other protocol requirements.
4. Patients w ith histologically proven peripheral T-cell lymphoma (PTCL), not previously treated; the follow ing subtypes as defined by the WHO classification (2008;2011) may be included, w hatever the Ann Arbor stage (I - IV): a. Nodal types: i. PTCL, not otherw ise specified ii. Angioimmunoblastic T-cell lymphoma iii. Anaplastic large cell lymphoma, ALK-negative type b. Extra-nodal types: i. Enteropathy-associated T-cell lymphoma ii. Hepato-splenic T-cell lymphoma iii. Subcutaneous panniculitis-like T-cell lymphoma iv. Primary cutaneous gamma-delta T-cell lymphoma v. Primary cutaneous CD8+ aggressive epidermotropic lymphoma vi. Primary cutaneous CD4+ small/medium T-cell lymphoma c. Other non classifiable peripheral T-cell lymphoma
5. ECOG performance status 0, 1 or 2
6. Negative pregnancy test for females of childbearing potential (FCBP)
7. Female patients of child bearing potential must use an effective method of birth control (i.e. hormonal contraceptive, intrauterine device, diaphragm w ith spermicide, condom w ith spermicide or abstinence) during treatment period and 1 month thereafter; Males must use an effective method of birth control during treatment period and 3 months thereafter.
8. Life expectancy of ≥ 90 days (3 months).

Exclusion Criteria:

1. Any significant medical condition, laboratory abnormality, or psychiatric illness that w ould prevent the patient from participating in the study.
2. Any condition that confounds the ability to interpret data from the study.
3. Other types of lymphomas, e.g. B-cell lymphoma
4. The follow ing types of T cell lymphomas:
    a. Adult T-cell lymphoma/leukemia (HTLV-1 related T-cell lymphoma)
    b. Extranodal T-cell/NK-cell lymphoma, nasal type
    c. Anaplastic large cell lymphoma, ALK-positive type
    d. Cutaneous T cell lymphoma (mycosis fungoid, Sézary syndrome)
    e. Primary cutaneous CD30+ T-cell lymphoproliferative disorder
    f. Primary cutaneous anaplastic T-cell lymphoma
5. Previous treatment for PTCL w ith immunotherapy or chemotherapy except for short-term corticosteroids (duration of ≤ 8 days) before randomization
6. Previous radiotherapy for PTCL except if localized to one lymph node area
7. Patients planned for autologous or allogeneic transplant as consolidation in first line
8. Central nervous system -meningeal involvement

9. Contraindication to any drug contained in the chemotherapy regimen,
10. Subjects with HIV positivity
11. Subjects with active hepatitis B or C. Chronic carriers of hepatitis B without HBV DNA positive blood are eligible. Subjects with non-active hepatitis C (with normal transaminases) are eligible.
12. Any of the following laboratory abnormalities, except if secondary to the lymphoma:
    a. Absolute neutrophil count (ANC) < 1,500 cells/mm3 (1.5 x 109/L),
    b. Platelet count < 100,000/mm3 (100 x 109/L), or < 75,000/mm3 if bone marrow is involved,
    c. Serum SGOT/AST or SGPT/ALT ≥ 3.0 x upper limit of normal (ULN),
    d. Serum total bilirubin > 2 x ULN, except in case of hemolytic anemia,
    e. K+ and Mg2+ levels < LLN, except if corrected per protocol guidance before beginning the romidepsin infusion
13. Serum creatinine > 2.0 x ULN
14. Prior history of malignancies other than lymphoma (except for basal cell or squamous cell carcinoma of the skin or carcinoma in situ of the cervix or breast or untreated prostatic cancer without any plan for a treatment) unless the patient has been free of the disease for ≥ 3 years
15. Any serious medical condition, laboratory abnormality, or psychiatric illness that would prevent the patient from signing the informed consent form
16. Any known cardiac abnormalities such as:
    a. Patients with congenital long QT syndrome
    b. Corrected QT interval > 480 msec (using the Fridericia formula)
    c. Myocardial infarction within 6 months of cycle 1 day 1
    d. History of or concomitant significant cardiovascular disease
    e. Ejection fraction <45% by MUGA scan or by echocardiogram;
17. Concomitant use of drugs that may cause a significant prolongation of the QTc
18. Patients who have received more than 200 mg/m2 doxorubicin
19. Concomitant use of strong CYP3A4 inhibitors
20. Concomitant use of therapeutic warfarin due to a potential drug interaction. Use of a low dose of warfarin or another anticoagulant to maintain patency of venous access port and cannulas is permitted.
21. Clinically significant active infection
22. Use of any standard or experimental anti-cancer drug therapy within 28 days of the initiation (Day 1) of study drug
23. Pregnant or lactating females or women of childbearing potential not willing to use an adequate method of birth control for the duration of the study.

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: NCT01796002

Contacts

Contact: O'Brian SAINDOY, PhD +33 4 72 66 93 33 obrian.saindoy@lysarc.org

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Show 131 Study Locations

Sponsors and Collaborators

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Investigators

Principal Investigator: Bertrand COIFFIER, Professor CH Lyon Sud, Pierre Bénite, France

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More Information

Additional Information:

MedlinePlus related topics: Lymphoma

Drug Information available for: Romidepsin

No publications provided

Responsible Party:	The Lymphoma Academic Research Organisation
ClinicalTrials.gov Identifier:	NCT01796002 History of Changes
Other Study ID Numbers:	**Ro-CHOP** Study
Study First Received:	January 31, 2013
Last Updated:	September 4, 2015
Health Authority:	France: Agence Nationale de Sécurité du Médicament et des produits de santé Belgium: Federal Agency for Medicines and Health Products, FAMHP Korea: Ministry of Food and Drug Safety Spain: Agencia Española de Medicamentos y Productos Sanitarios Italy: The Italian Medicines Agency Germany: Federal Institute for Drugs and Medical Devices Portugal: INFARMED, National Authority of Medicines and Health Products, IP Singapore: Health Sciences Authority

Keywords provided by The Lymphoma Academic Research Organisation:
PTCL

Additional relevant MeSH terms:

Lymphoma	Neoplasms
Lymphoma, T-Cell	Neoplasms by Histologic Type
Lymphoma, T-Cell, Peripheral	Romidepsin
Immune System Diseases	Antibiotics, Antineoplastic
Immunoproliferative Disorders	Antineoplastic Agents
Lymphatic Diseases	Pharmacologic Actions
Lymphoma, Non-Hodgkin	Therapeutic Uses
Lymphoproliferative Disorders	

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