

History of Changes for Study: NCT00644124

Aflibercept and Standard Chemotherapy (R-CHOP) in First Line of Non Hodgkin B-CLL

[Latest version \(submitted May 5, 2016\) on ClinicalTrials.gov](#)

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The selection applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently selected.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in red.
- Study additions are displayed in green.

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Ex

Study Record Versions

| Version | A | B | Submitted Date | Changes |
|---------|----------------------------------|----------------------------------|--------------------------------|-----------------------------------|
| 1 | <input checked="" type="radio"/> | <input checked="" type="radio"/> | March 21, 2008 | None (earliest Version on record) |
| 2 | <input type="radio"/> | <input type="radio"/> | April 25, 2008 | Study Status |

| Version | A | B | Submitted Date | Changes |
|---------|-----------------------|-----------------------|------------------------------------|---|
| 4 | <input type="radio"/> | <input type="radio"/> | September 19, 2008 | Study Status, Outcome Measures and Study Identification |
| 5 | <input type="radio"/> | <input type="radio"/> | March 3, 2009 | Study Status |
| 6 | <input type="radio"/> | <input type="radio"/> | March 10, 2009 | Recruitment Status, Contacts/Locations and Study Status |
| 7 | <input type="radio"/> | <input type="radio"/> | August 30, 2011 | Sponsor/Collaborators, Study Status, Study Identification and References |
| 8 | <input type="radio"/> | <input type="radio"/> | January 3, 2012 | Recruitment Status, Study Status and Study Design |
| 9 | <input type="radio"/> | <input type="radio"/> | May 5, 2016 | Arms and Interventions, Study Status, Study Design and Study Identification |

[Compare](#)

Comparison Format: Merged
 Side-by-Side

[Scroll up to access the controls](#)

Study NCT00644124

Submitted Date: March 21, 2008 (v1)

▼ **Study Identification**

Unique Protocol ID: TCD10173

Brief Title: Aflibercept and Standard Chemotherapy (R-CHOP) in First Line of Non Hodgkin L

Official Title: A Phase I Open-Label Dose-Escalation Study of Intravenous Aflibercept (AVE0005) in Combination With R-CHOP Administered Every 2 Weeks or Every 3 Weeks in Patients With Diffuse Large B-Cell Lymphoma
 Hodgkin's B-Cell Lymphoma

Secondary IDs: AVE0005

EudraCT 2007-003737-16

▼ **Study Status**

Record Verification: March 2008

Overall Status: Recruiting

Study Start: March 2008

Primary Completion:

Study Completion:

First Submitted: March 21, 2008

First Submitted that March 21, 2008

Met QC Criteria:

First Posted: March 26, 2008 [Estimate]

Last Update Submitted that March 21, 2008

Met QC Criteria:

Last Update Posted: March 26, 2008 [Estimate]

▼ **Sponsor/Collaborators**

Sponsor: Sanofi

Responsible Party:

Collaborators: Regeneron Pharmaceuticals

▼ **Oversight**

U.S. FDA-regulated Drug:

U.S. FDA-regulated Device:

Data Monitoring: No

▼ **Study Description**

Brief Summary: The purpose of this study is to determine the selected dose of aflibercept when it is administered with R-CHOP treatment (Rituximab/Cyclophosphamide/Doxorubicin/Vincristine/Prednisone/Methotrexate) administered every 2 weeks or every 3 weeks, in non Hodgkin B-cell lymphoma. The study will also determine how the body handles aflibercept when it is administered with R-CHOP.

Detailed Description:

▼ **Conditions**

Conditions: Lymphoma, Non-Hodgkin

Keywords: Non-Hodgkin's lymphoma
angiogenesis inhibitors
CHOP protocol

▼ **Study Design**

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 1

Interventional Study Model: Parallel Assignment

Number of Arms:

Masking: None (Open Label)

Allocation: Non-Randomized

Enrollment: 50 [Anticipated]

▼ **Arms and Interventions**

Intervention Details:

Drug: aflibercept
in combination with standard treatment R-CHOP

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