



## Dose Ranging Study of RPC4046 in Eosinophilic Esophagitis

**CLINICALTRIALS.GOV IDENTIFIER**  
NCT02098473

**RECRUITMENT STATUS**  
COMPLETED

**FIRST POSTED**  
MARCH 28, 2014

**LAST UPDATE POSTED**  
MAY 9, 2017

### STUDY DESCRIPTION

#### Brief Summary

The purpose of this study is to determine the effective dose(s) of RPC4046 in the treatment of Eosinophilic Esophagitis (EoE). This trial consists of two phases: 16 weeks of double-blind treatment and 52 weeks of open-label extension.

**Condition or Disease:** Eosinophilic Esophagitis

**Intervention/treatment:** Drug: RPC4046  
Drug: Placebo

**Phase:** Phase 2

### DETAILED DESCRIPTION

N/A

### STUDY DESIGN

**Study Type:** Interventional  
**Estimated Enrollment :** 100 participants  
**Intervention Model :** Parallel Assignment  
**Masking:** Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)  
**Primary Purpose:** Treatment  
**Official Title:** A Phase2, Multi-Center, Multi-national, Randomized, Double-blind, Placebo-controlled Parallel-group Clinical Trial to Evaluate the Efficacy and Safety of RPC4046 in Adult Subjects With Eosinophilic Esophagitis

**Actual Study Start Date:** August 2014  
**Actual Primary Completion Date:** February 2016  
**Actual Study Completion Date:** January 2017

### ARMS AND INTERVENTIONS

Arm	Intervention/treatment
Experimental: RPC4046 High Dose intravenous (IV) infusion only once at first dose, 2 subcutaneous (SC) injections weekly for 16 weeks, high dose	Drug: RPC4046
Experimental: RPC4046 Low Dose intravenous (IV) infusion only once at first dose, 2 subcutaneous (SC) injections weekly for 16 weeks, low dose	Drug: RPC4046
Placebo Comparator: Placebo intravenous (IV) infusion only once at first dose, 2 subcutaneous (SC) injections weekly for 16 weeks	Drug: Placebo

### OUTCOME MEASURES

Primary Outcome Measures: 1. Mean Eosinophil Count [ Time Frame: Week 16 ]

### ELIGIBILITY CRITERIA

**Ages Eligible for Study:** 18 to 65 Years (Adult, Older Adult)

**Sexes Eligible for Study:** All

**Accepts Healthy Volunteers:** No

#### Criteria

Inclusion Criteria:

- Histologic evidence of EoE
- Clinical symptoms of EoE including dysphagia

Exclusion Criteria:

- Primary causes of esophageal eosinophilia other than EoE

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## CONTACTS AND LOCATIONS

### Contacts

#### Locations

United States, Arizona	Mayo Clinic - Arizona	Scottsdale
United States, Arizona	Desert Sun Clinical Research, LLC	Tucson
United States, California	Alliance Clinical Research	Oceanside
United States, California	Precision Research Institute, LLC	San Diego
United States, Colorado	University of Colorado School of Medicine	Aurora
United States, Connecticut	Connecticut Clinical Research Foundation	Bristol
United States, Florida	University of Florida	Gainesville
United States, Florida	Borland-Groover Clinic	Jacksonville
United States, Georgia	Children's Center for Digestive Healthcare	Atlanta
United States, Idaho	Grand Teton Research Group	Idaho Falls
United States, Illinois	Northwestern University-Feinberg School of Medicine	Chicago
United States, Illinois	Southwest Gastroenterology	Oak Lawn
United States, Indiana	Indiana University	Indianapolis
United States, Iowa	University of Iowa Hospitals and Clinics	Iowa City
United States, Maryland	Gastroenterology and Hepatology Service Walter Reed National Military Medical Center	Bethesda
United States, Maryland	Metropolitan Gastroenterology Group Chevy Chase Clinical Research	Chevy Chase
United States, Michigan	West Michigan Clinical Research Center Gastroenterology Associates of Western Michigan	Wyoming
United States, Minnesota	Minnesota Gastroenterology	Plymouth
United States, Mississippi	GI Associates and Endoscopy Center-GI Clinical Research Department	Flowood
United States, New Hampshire	Dartmouth Hitchcock Medical Center	Lebanon
United States, North Carolina	Asheville Gastroenterology Associates, PA	Asheville
United States, North Carolina	University of North Carolina	Chapel Hill
United States, Ohio	Cincinnati Children's Hospital Medical Center	Cincinnati
United States, Ohio	Great Lakes Gastroenterology Research	Mentor
United States, Pennsylvania	University of Pennsylvania Perelman Center for Advanced Medicine	Philadelphia
United States, Tennessee	Vanderbilt University	Nashville
United States, Utah	University of Utah Division of Gastroenterology	Salt Lake City
Canada, Alberta	Gastrointestinal Research Group, University of Calgary Health	Calgary
Switzerland	Centre Hospitalier Universitaire Vaudois (CHUV)	Lausanne
Switzerland	Swiss EoE Clinic	Olten

### Sponsors and Collaborators

Celgene

### Investigator

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## MORE INFORMATION

<b>Responsible Party :</b>	Celgene
<b>ClinicalTrials.gov Identifier :</b>	NCT02098473
<b>Other Study ID Numbers :</b>	RPC02-201
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**Additional relevant** *Esophagitis*

**MeSH terms :**

*Eosinophilic Esophagitis*