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A Safety and Efficacy Study for Infliximab (Remicade) in Patients With Ulcerative Colitis

This study has been completed.

Sponsor:

Centocor, Inc.

Information provided by:

Centocor, Inc.

ClinicalTrials.gov Identifier:

NCT00096655

First received: November 12, 2004

Last updated: May 16, 2011

Last verified: March 2010

[History of Changes](#)

[Full Text View](#)
[Tabular View](#)
[No Study Results Posted](#)
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Tracking Information

First Received Date ICMJE	November 12, 2004
Last Updated Date	May 16, 2011
Start Date ICMJE	May 2002
Primary Completion Date	<i>Not Provided</i>
Current Primary Outcome Measures ICMJE (submitted: March 6, 2008)	The proportion of patients with clinical response, defined as a decrease from baseline in the Mayo score by = 30% and = 3 points, with a decrease in the rectal bleeding subscore of = 1 or a rectal bleeding subscore of 0 or 1, at week 8 .
Original Primary Outcome Measures ICMJE	<i>Not Provided</i>
Change History	Complete list of historical versions of study NCT00096655 on ClinicalTrials.gov Archive Site
Current Secondary Outcome Measures ICMJE (submitted: March 29, 2010)	Achievement of clinical remission defined as a Mayo score of = 2 points, with no individual subscore > 1 at week 8. Patients in remission will have a rectal bleeding subscore of either 0 or 1, patients who demonstrate mucosal healing at week 8.
Original Secondary Outcome Measures ICMJE	<i>Not Provided</i>
Current Other Outcome Measures ICMJE	<i>Not Provided</i>
Original Other Outcome Measures ICMJE	<i>Not Provided</i>

Descriptive Information

Brief Title ICMJE	A Safety and Efficacy Study for Infliximab (Remicade) in Patients With Ulcerative Colitis
Official Title ICMJE	A Randomized, Placebo-controlled, Double-blind Trial to Evaluate the Safety and Efficacy of Infliximab in Patients With Active Ulcerative Colitis
Brief Summary	The purpose of this study is to evaluate the effectiveness and safety of infliximab (Remicade) in patients with Ulcerative Colitis. Infliximab (Remicade) targets specific proteins in the body's immune system to help control the

	development of inflammation to help reduce painful disease.
Detailed Description	This study is designed to investigate the safety and effectiveness of infliximab in adult patients with active ulcerative colitis. The purpose of this study is to see if the symptoms of ulcerative colitis are lessened with this medication infliximab, and what dose is needed to do that safely. Patients will receive infusions of either 5 or 10 mg/kg or placebo at weeks 0, 2, 6, 14, and 22 up to week 164. Safety evaluations will be performed at specified intervals throughout the study and will consist of laboratory tests, vital signs (such as blood pressure), physical examinations and the occurrence and severity of adverse events as well as other study specific procedures. Patients will receive infusions (into the vein) of either 5 or 10 mg/kg or placebo at weeks 0, 2, 6, and every 8 weeks up to week 164.
Study Type ICMJE	Interventional
Study Phase	Phase 3
Study Design ICMJE	Allocation: Randomized Endpoint Classification: Safety/Efficacy Study Intervention Model: Parallel Assignment Masking: Double-Blind Primary Purpose: Treatment
Condition ICMJE	Ulcerative Colitis
Intervention ICMJE	Drug: Infliximab
Study Arm (s)	<i>Not Provided</i>
Publications *	- Feagan BG, Reinisch W, Rutgeerts P, Sandborn WJ, Yan S, Eisenberg D, Bala M, Johanns J, Olson A, Hanauer SB. The effects of infliximab therapy on health-related quality of life in ulcerative colitis patients. <i>Am J Gastroenterol.</i> 2007 Apr;102(4):794-802. Epub 2007 Feb 23. Erratum in: <i>Am J Gastroenterol.</i> 2007 Jun;102(6):1338. - Reinisch W, Sandborn WJ, Bala M, Yan S, Feagan BG, Rutgeerts P, Radford-Smith G, Xu S, Eisenberg D, Olson A, Colombel JF. Response and remission are associated with improved quality of life, employment and disability status, hours worked, and productivity of patients with ulcerative colitis. <i>Inflamm Bowel Dis.</i> 2007 Sep;13(9):1135-40. - Rutgeerts P, Sandborn WJ, Feagan BG, Reinisch W, Olson A, Johanns J, Travers S, Rachmilewitz D, Hanauer SB, Lichtenstein GR, de Villiers WJ, Present D, Sands BE, Colombel JF. Infliximab for induction and maintenance therapy for ulcerative colitis. <i>N Engl J Med.</i> 2005 Dec 8;353(23):2462-76. - Colombel JF, Rutgeerts P, Reinisch W, Esser D, Wang Y, Lang Y, Marano CW, Strauss R, Oddens BJ, Feagan BG, Hanauer SB, Lichtenstein GR, Present D, Sands BE, Sandborn WJ. Early mucosal healing with infliximab is associated with improved long-term clinical outcomes in ulcerative colitis. <i>Gastroenterology.</i> 2011 Oct;141(4):1194-201. Epub 2011 Jun 30. - Sandborn WJ, Rutgeerts P, Feagan BG, Reinisch W, Olson A, Johanns J, Lu J, Horgan K, Rachmilewitz D, Hanauer SB, Lichtenstein GR, de Villiers WJ, Present D, Sands BE, Colombel JF. Colectomy rate comparison after treatment of ulcerative colitis with placebo or infliximab. <i>Gastroenterology.</i> 2009 Oct;137(4):1250-60; quiz 1520. Epub 2009 Jul 28.
* Includes publications given by the data provider as well as publications identified by ClinicalTrials.gov Identifier (NCT Number) in Medline.	
Recruitment Information	
Recruitment Status ICMJE	Completed
Enrollment ICMJE	364
Completion Date	August 2007
Primary Completion Date	<i>Not Provided</i>
Eligibility Criteria ICMJE	Inclusion Criteria: Patients must have had ulcerative colitis of at least 3 months' duration at screening, confirmed by the biopsy taken at screening

	• Patients must have active colitis confirmed during the screening sigmoidoscopy • Patients must have active disease. Exclusion Criteria: • Patient must not be likely to require surgical removal of all or part of the colon within 12 weeks of beginning the study • Patient must not require, or required within the 2 months prior to beginning the study, surgery for active gastrointestinal bleeding, peritonitis, intestinal obstruction, or intra-abdominal or pancreatic abscess requiring surgical drainage				
Gender	Both				
Ages	18 Years and older				
Accepts Healthy Volunteers	Yes				
Contacts ICMJE	Contact information is only displayed when the study is recruiting subjects				
Location Countries ICMJE	Not Provided				
Administrative Information					
NCT Number ICMJE	NCT00096655				
Other Study ID Numbers ICMJE	CR004783				
Has Data Monitoring Committee	Not Provided				
Responsible Party	Not Provided				
Study Sponsor ICMJE	Centocor, Inc.				
Collaborators ICMJE	Not Provided				
Investigators ICMJE	<table border="1"> <tr> <td>Study Director:</td> <td>Centocor, Inc. Clinical Trial</td> <td>Centocor, Inc.</td> <td></td> </tr> </table>	Study Director:	Centocor, Inc. Clinical Trial	Centocor, Inc.	
Study Director:	Centocor, Inc. Clinical Trial	Centocor, Inc.			
Information Provided By	Centocor, Inc.				
Verification Date	March 2010				
ICMJE Data element required by the International Committee of Medical Journal Editors and the World Health Organization ICTRP					