Trial record **5 of 5** for: vedolizumab | Brazil

Previous Study | Return to List | Next Study

Non-interventional Study of Moderate to Severe Inflammatory Bowel Disease in Brazil

ClinicalTrials.gov Identifier: NCT02822235

Recruitment Status : Completed
First Posted : July 4, 2016
Results First Posted : February 25, 2020
Last Update Posted : February 25, 2020

Sponsor:
Takeda

Information provided by (Responsible Party):
Takeda

Study Details | Tabular View | Study Results | Disclaimer | How to Read a Study Record

Study Description

Go to

Brief Summary:

The purpose of this study is to gather information regarding the population with moderate to severe inflammatory bowel disease (IBD), the burden of the disease, and understand their treatment patterns, particularly on the use of available biologic therapies.

Condition or disease	Intervention/treatment
Inflammatory Bowel Disease	Other: No Intervention

Detailed Description:

This is a non-interventional study to determine the rate of control of disease activity in moderate to severe inflammatory bowel disease (IBD) participants, with two parts: cross-sectional evaluation (Day 1) with retrospective data collection and a prospective 12-month evaluation for patients with active IBD at cross-sectional evaluation (Day 1).

The study enrolled 407 patients. This multicenter trial was conducted in Brazil. Retrospective data of previous IBD treatments (drug, dose, treatment duration, drug changes), and use of other health resources related with the management of IBD for previous three years will be collected. Prospective data was collected for a period of 12 months in participants with active disease. UC participants, with no or light disease activity at Day 1 did not continue to 12-month follow up. CD participants, with no or light disease activity at Day 1 but with colonoscopy or calprotectin levels (i.e, calprotectin >200 ug/g) in the previous year suggestive of inadequate control of activity progressed to 12-month follow up.

Study Design

Go to

Study Type :
Observational

Actual Enrollment :
407 participants

Observational Model:
Cohort

Time Perspective:
Prospective

Official Title:
Real-world Data of Moderate to Severe Inflammatory Bowel Disease in Brazil: a Non-interventional, Multicenter Study to Evaluate Disease Control, Treatment Patterns, Burden of Disease and Quality of Life (RISE BR)

Actual Study Start Date :
October 11, 2016

Actual Primary Completion Date :

February 5, 2018

Actual Study Completion Date :

February 19, 2018

Resource links provided by the National Library of Medicine

MedlinePlus related topics: Crohn's Disease

U.S. FDA Resources

Groups and Cohorts

Go to

Group/Cohort	Intervention/treatment
Crohn's Disease Participants with diagnosis of moderate to severe Crohn's disease (CD) for at least 6 months prior to Day 1 were observed to collect the retrospective data including previous inflammatory bowel disease (IBD) treatments (drug dose, treatment duration, drug changes), and use of other health resources related with the management of IBD for previous three years at Day 1. Participants with active IBD and CD at Day 1 were followed up for 12 months in prospective phase.	Other: No Intervention

Group/Cohort	Intervention/treatment
Ulcerative Colitis Participants diagnosed with diagnosis of moderate to severe ulcerative colitis (UC) for at least 6 months prior to Day 1 were observed to collect the retrospective data including previous inflammatory bowel disease (IBD) treatments (drug dose, treatment duration, drug changes), and use of other health resources related with the management of IBD for previous three years at Day 1. Participants with active IBD and UC at Day 1 were followed up for 12 months in prospective phase.	Other: No Intervention

Outcome Measures

Go to

Primary Outcome Measures :

1. Percentage of Participants With Active Crohn's Disease (CD) at Day 1 [Time Frame: Day 1]

   Participants with Harvey Bradshaw Index (HBI) score of ≥8 or Crohn´s Disease Activity Index (CDAI) ≥220 points at Day 1 were classified as participants with active disease. HBI scale assessed five dimensions (general well-being, abdominal pain, number of liquid stools per day, abdominal mass, and complications). These dimensions were scored from the previous day. The total score ranges from 0 to 25. The CDAI evaluated the severity of signs and symptoms of CD. Collected data included information on the number of liquid stools, intensity of abdominal pain, general well-being, presence of comorbid conditions, use of medications for diarrhea, physical examination, and laboratory findings (abdominal mass, hematocrit, body weight), yielding 8 items that were combined with data from a 7-day diary to obtain the total CDAI score which ranges from 0 to approximately 600 points, where higher score indicates higher disease activity.

2. Number of Participants With Active Ulcerative Colitis (UC) at Day 1 [Time Frame: Day 1]

   Participants with ≥5 points in Partial Mayo Score were classified as active UC disease. The mayo score without endoscopy measured severity of ulcerative colitis. Three sub-scores for stool frequency, rectal bleeding, and physician's global assessment were each graded from 0 to 3 with higher scores indicating more severe disease. Individual sub-scores were then summed to provide the total score ranging from 0 (normal or inactive disease) to 9 (severe disease).

Secondary Outcome Measures :

1. Number of Participants With Moderate to Severe CD or UC Stratified by Age, Gender, Professional Status, Family History, Educational Level and Income at Day 1 [Time Frame: Day 1]
2. Number of Participants With Moderate to Severe CD or UC Stratified by Clinical Variables [Time Frame: Day 1]

   Clinical variables included IBD type:CD/UC; anthropometric (Height, Weight and BMI); Family history; Smoking habits; Medical History/Comorbidities; Disease location -L1=ileal, L2=colonic disease, L3=ileocolic, L4=isolated upper GI tract disease location. Behavior as B1/B1+P=Non stenosing/non penetrating or B1+P=Non stenosing/non penetrating+perianal disease, B2/B2+P=Stenosing/B2+P=Stenosing+perianal disease B3/B3+P=Penetrating, B3+P=Penetrating+perianal disease, P=Penetrating disease. Extension of inflammation as E1=distal UC: proctitis or E1=distal UC: proctosigmoiditis extension of inflammation E2/E3=left-sided: mucosa inflammation extending up to splenic flexure or E3=pancolitis: mucosa inflammation up to proximal transverse colon and beyond extension of inflammation and severity of UC as S0=Clinical remission, S1=Mild UC, S2=Moderate UC, S3=Severe UC. Steroid behavior; Colonoscopy, Calprotectin levels >200ug/g, Eligibility for 12-month follow-up.

3. Percentage of Participants With Moderate to Severe CD or UC Who Used Various Types of Therapies for IBD in Previous 3 Years [Time Frame: Within the previous 3 years including Day 1]

   Therapies for IBD included aminosalicylates, steroids, immunossupressors, biologics, antibiotics, surgeries and others. One participant could use more than one therapy.

4. Percentage of Participants With Moderate to Severe CD or UC Treated With Biologic Therapy Within 3 Previous Years [Time Frame: Within the previous 3 years including Day 1]

   IBD types included CD and UC. Biologic therapies included treatment with infliximab, adalimumab, **vedolizumab**, certolizumab, golimumab and ustekimumab. One participant could use more than one biologic therapy.

5. Percentage of Participants With Moderate to Severe CD or UC Who Have Not Responded Previously to Biologic Therapies [Time Frame: Day 1]

   IBD types included CD and UC. Biologic therapies included treatment with infliximab, adalimumab, **vedolizumab**, certolizumab, golimumab and ustekimumab.

6. Percentage of Participants With Moderate to Severe CD or UC Who Were Ongoing IBD Treatment at Day 1 [Time Frame: Day 1]

   Participants with moderate to severe CD or UC ongoing IBD treatment at Day 1 were reported.

7. Number of Participants With Moderate to Severe Activity of CD or With Light or no Activity Stratified by Socio-demographic Variables [Time Frame: Day 1]

   Socio-demographic variables included gender and professional status.

8. Number of Participants With Moderate to Severe Activity of CD or With Light or no Activity Stratified by Clinical Variables [Time Frame: Day 1]

   Clinical variables included IBD type:CD/UC; Family history; Smoking habits; Medical History/Comorbidities; Disease location -L1=ileal, L2=colonic disease, L3=ileocolic, L4=isolated upper GI tract disease location. Behavior as B1/B1+P=Non stenosing/non penetrating or B1+P=Non stenosing/non penetrating+perianal disease, B2/B2+P=Stenosing/B2+P=Stenosing+perianal disease B3/B3+P=Penetrating, B3+P=Penetrating+perianal disease, P=Penetrating disease. Steroid behavior; Colonoscopy, Calprotectin levels >200ug/g.

9. Percentage of Participants With Treatment Beginning or Ongoing at Day 1 by Moderate to Severe Activity of CD or With Light or no Activity Stratified by Treatment Variables [Time Frame: Day 1]

   Treatment variables included previous treatments or regimens (aminosalicylates, steroids, immunossupressors, biologics, antibiotics); and previous surgeries for IBD. One participant could use more than one treatment regimens.

10. Number of Participants With Moderate to Severe Activity of UC or With Light or no Activity Stratified by Socio-demographic Variables [Time Frame: Day 1]

    Socio-demographic variables included gender and professional status.

11. Number of Participants With Moderate to Severe Activity of UC or With Light or no Activity Stratified by Clinical Variables [Time Frame: Day 1]

    Clinical variables included IBD type:CD/UC; Family history; Smoking habits; Medical History/Comorbidities; Extension of inflammation as E1=distal UC: proctitis or E1=distal UC: proctosigmoiditis extension of inflammation E2/E3=left-sided: mucosa inflammation extending up to splenic flexure or E3=pancolitis: mucosa inflammation up to proximal transverse colon and beyond extension of inflammation and severity of UC as S0=Clinical remission, S1=Mild UC, S2=Moderate UC, S3=Severe UC. Steroid behavior; Colonoscopy, Calprotectin levels >200ug/g.

12. Percentage of Participants With Treatment Beginning or Ongoing at Day 1 by Moderate to Severe Activity of UC or With Light or no Activity Stratified by Treatment Variables [Time Frame: Day 1]

    Treatment variables include previous treatments or regimens (aminosalicylates, steroids, immunomodulators, immunossupressors, biologics, antibiotics); and previous surgeries for IBD. One participant could use more than one treatment regimens.

13. Harvey Bradshaw Index (HBI) Total Score in Participants Who Had Moderate to Severe Active CD at Day 1 and Month 12 [Time Frame: Day 1 and Month 12]

    HBI scale assessed the severity of CD. HBI scale assessed five dimensions (general well-being, abdominal pain, number of liquid stools per day, abdominal mass, and complications). These dimensions were scored from the previous day. The total score ranges from 0 to 25. Higher score indicates higher disease activity.

14. Crohn´s Disease Activity Index (CDAI) Total Score in Participants Who Had Moderate to Severe Active CD at Day 1 and Month 12 [Time Frame: Day 1 and Month 12]

    CDAI evaluated the severity of signs and symptoms of CD. Collected data included information on the number of liquid stools, intensity of abdominal pain, general well-being, presence of comorbid conditions, use of medications for diarrhea, physical examination, and laboratory findings (abdominal mass, hematocrit, body weight), yielding 8 items that were combined with data from a 7-day diary to obtain the total CDAI score which ranges from 0 to approximately 600 points, where higher score indicates higher disease activity.

15. Partial Mayo Score in Participants Who Had Moderate to Severe Active UC at Day 1 and Month 12 [Time Frame: Day 1 and Month 12]

    The mayo score without endoscopy measured severity of ulcerative colitis. Three sub-scores for stool frequency, rectal bleeding, and physician's global assessment were each graded from 0 to 3 with higher scores indicating more severe disease. Individual sub-scores were then summed to provide the total score ranging from 0 (normal or inactive disease) to 9 (severe disease).

16. Percentage of Participants With Moderate to Severe Active CD or UC Who Changed IBD Treatment at Month 12, by Reason [Time Frame: Month 12]

    One participant could have more than one reason for discontinuation.

17. Quality of Life as Assessed by European Quality of Life 5-Dimension (EQ-5D) Health States Visual Analog Scale (VAS) Score at Day 1 [Time Frame: Day 1]

    EQ-5D questionnaire is an instrument used to measure general HRQOL in participants with IBD. Each dimension has three possible levels: 1 = none, 2 = moderate or 3 = extreme. The EQ-5D VAS score is a self-assigned rating of overall health using a 20-cm visual, vertical scale, with a score of 0 as the worst and 100 as the best possible health. An increase of ≥7 points in the EQ-5D VAS score represents a clinically meaningful improvement in quality of life for participants.

18. Quality of Life as Assessed by 36-Item Short Form Health Survey (SF-36) Component Score at Day 1 [Time Frame: Day 1]

    The Short Form-36 (SF-36) is a questionnaire that evaluates a participant's health related quality of life. SF-36 includes 36 questions related to 8 health dimensions: physical functioning, role-physical (role limitations due to physical health problems), bodily pain, general health, vitality (energy/fatigue), social functioning, role-emotional (role limitations due to emotional problems), and mental health. Based on these 4 scales (physical functioning, role-physical, bodily pain, general health), the physical component summary (PCS) score is generated which ranges between 0 and 100, with higher scores indicating a better quality of life. Based on these 4 scales (vitality, social functioning, role-emotional, and mental health), the mental component summary (MCS) score is generated which ranges between 0 and 100, with higher scores indicating a better quality of life.

19. Inflammatory Bowel Disease Questionnaire (IBDQ) Total Score at Day 1 [Time Frame: Day 1]

    The Inflammatory Bowel Disease Questionnaire (IBDQ) was a 32-item questionnaire that measures 4 dimensions: bowel function, emotional status, systemic symptoms, and social function. Within dimensions, each question presented seven possible answers/points. Each domain score was the sum of 8 responses each ranging from 1 to 7, where 1 indicated worst function and 7 the best. The total score ranged from 32 to 224, with higher scores representing better quality of life. The IBDQ was not validated for participants with colostomies and therefore was not be applied for these participants.

20. Inflammatory Bowel Disease Questionnaire (IBDQ) Domain Score at Day 1 [Time Frame: Day 1]

    The Inflammatory Bowel Disease Questionnaire (IBDQ) was a 32-item questionnaire that measures 4 dimensions: bowel function, emotional status, systemic symptoms, and social function. Within dimensions, each question presented seven possible answers/points. Each domain score was the average of 8 responses each ranging from 1 to 7, where 1 indicated worst function and 7 the best function. The IBDQ was not validated for participants with colostomies and therefore was not be applied for these participants.

21. Mean of Percentage of Total Work Impairment Due to CD as Assessed by Work Productivity and Activity Impairment (WPAI) Questionnaire at Day 1 [Time Frame: Day 1]

    The Work Productivity and Activity Impairment questionnaire (WPAI) assessed the impact of IBD on work productivity and daily activities during the previous 7 days. The 'impairment while working due to IBD' was calculated based on one question: to what degree did the disease impair the productivity while working in the past seven days from visit and the 'activity impairment' was calculated based on Question: how much did the disease affect ability to perform regular daily activities, other than work at a job? Percentage of overall work impairment due to IBD is calculated as: Absenteeism+(1-

Absenteeism)*Presenteeism. The total score ranges from 0 (no impairment) to 100% (total loss of work productivity).

22. Mean of Percentage of Work Time Missed Due to CD as Assessed by WPAI at Day 1
[Time Frame: Day 1]

Mean total activity impairment due to IBD from WPAI questionnaire was reported. The 'overall work impairment due to IBD' was calculated based on three items: (Q2) the number of hours missed from work due to health problems in the past seven days; (Q4) the number of actual work hours in the past seven days; and (Q5) to what degree did the disease impair the productivity while working past seven days. The data was calculated using the formula Q2/(Q2+Q4)+[(1-(Q2/(Q2+Q4))x(Q5/10)] and converted to percent. Data are presented as impairment percentage, with higher numbers indicating greater impairment and less productivity.

23. Mean of Percentage of Impairment While Working Due to CD as Assessed by WPAI at Day 1
[Time Frame: Day 1]

Mean impairment while working due to IBD from WPAI questionnaire was reported. The 'impairment while working due to IBD' was calculated based on one item: (Q5) to what degree did the disease impair the productivity while working in the past seven days. The item was measured on a scale from 0 (no effect) to 10 (completely prevented from doing regular activities/ working). The data was calculated using the formula Q5/10 and converted to percent. ata are presented as impairment percentage, with higher numbers indicating greater impairment and less productivity.

24. Mean of Percentage of Total Activity Impairment Due to CD as Assessed by WPAI
[Time Frame: Day 1]

Mean total activity impairment due to IBD from WPAI questionnaire was reported. The 'overall work impairment due to IBD' was calculated based on three items: (Q2) the number of hours missed from work due to health problems in the past seven days; (Q4) the number of actual work hours in the past seven days; and (Q5) to what degree did the disease impair the productivity while working past seven days. The data was calculated using the formula Q2/(Q2+Q4)+[(1-(Q2/(Q2+Q4))x(Q5/10)] and converted to percent. Data are presented as impairment percentage, with higher numbers indicating greater impairment and less productivity.

25. Percentage of Participants Who Used Healthcare Resources [Time Frame: Day 1]

Healthcare resources used in the previous 3 years included imaging and laboratory testing, surgeries, hospitalizations, and consultations.

Eligibility Criteria

Go to

Information from the National Library of Medicine

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, Learn About Clinical Studies.

Ages Eligible for Study:

18 Years and older (Adult, Older Adult)

Sexes Eligible for Study:

All

Accepts Healthy Volunteers:

No

Sampling Method:

Non-Probability Sample

Study Population

Adult participants diagnosed with moderate to severe Crohn's Disease (CD) or Ulcerative Colitis (UC) were observed.

Criteria

Inclusion Criteria:

1. Male or female.
2. 18 years or older (at the time of diagnosis of moderate to severe UC or CD).
3. Diagnosis of moderate to severe CD or UC for at least 6 months prior to Day 1 appointment according the clinical or endoscopic \ criteria.
4. Has provided the written informed consent. For the prospective period, eligible participants should present at least one of the following criteria that will only be applied at Day 1:
5. For CD participants:
   - Harvey Bradshaw Index (HBI) ≥8 or
   - Crohn's Disease Activity Index (CDAI) ≥220 or Considering that for CD participants, the disease activity may not be clearly documented only with clinical data, some objective criteria may be considered as entry criteria for the 12-month prospective period:
   - Colonoscopy in the previous year suggestive of inadequate control of activity or,

- Calprotectin levels in the previous year suggestive of inadequate control of activity (i.e, calprotectin >200 µg/g).

6. For UC: partial Mayo Score ≥5.

Note: Participants with colostomy and prospective period: Although clinical scales defined above are impacted by colostomy these participants will not be excluded from the protocol to ensure the assessment of different clinical presentations of the IBD. In addition, participants with colostomy must follow the same criteria as above to be eligible to the prospective phase.

Exclusion Criteria:

1. Indeterminate or not classified colitis.
2. Current or previous participation in interventional clinical trial (within the last 3 years). In addition, for the 12-month prospective period, participants will be excluded if:
3. Presenting mental incapacity, unwillingness or language barriers precluding adequate understanding or cooperation.
4. Hospitalized participants at Day 1.
5. Current off label treatment with Vedolizumab.

Study Discontinuation Criteria It will be considered a premature termination the situation in which the participant discontinues the participation, i.e. they are withdrawn from the study before completing the 12 months of follow up period (365 days ± 14 days from Day 1), due to any of the reasons listed below:

1. Withdrawal of consent: participants who for any reason withdraw the free and informed consent;
2. Lost to follow-up (no return of the participant on the expected date of visit - drop-out from the protocol);
3. Death;
4. Study termination;
5. Any situation that places the participant within one of the exclusion criteria.

Note: Participants who are eligible for the prospective period, it means, with active disease at Day 1 but who during the 12 months period presents disease remission and/or no activity disease condition, are allowed to continue the participation in the study.

Contacts and Locations

Go to

Information from the National Library of Medicine

To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT02822235***

Locations

Brazil

Salvador, Bahia, **Brazil**

Goiania, Goias, **Brazil**

Belo Horizonte, Minas Gerais, **Brazil**

Juiz de Fora, Minas Gerais, **Brazil**

Curitiba, Parana, **Brazil**

Teresina, Piaui, **Brazil**

Porto Alegre, Rio Grande Do Sul, **Brazil**

Botucatu, Sao Paulo, **Brazil**

Ribeirao Preto, Sao Paulo, **Brazil**

Santo Andre, Sao Paulo, **Brazil**

Sao Jose do Rio Preto, Sao Paulo, **Brazil**

Rio de Janeiro, **Brazil**

Sao Paulo, **Brazil**

Sponsors and Collaborators

Takeda

Investigators

Study Director: Abner Augusto Lobão Neto Clinical Science Takeda

Study Documents (Full-Text)

Documents provided by Takeda:

Study Protocol [PDF] October 17, 2016

Statistical Analysis Plan [PDF] January 30, 2018

More Information

Go to

Responsible Party:

Takeda

ClinicalTrials.gov Identifier:

NCT02822235 History of Changes

Other Study ID Numbers:

Vedolizumab-4008

U1111-1178-66445 (Registry Identifier: WHO)

First Posted:

July 4, 2016 Key Record Dates

Results First Posted:

February 25, 2020

Last Update Posted:

February 25, 2020

Last Verified:

February 2020

Individual Participant Data (IPD) Sharing Statement:

Plan to Share IPD:

Yes

Plan Description:

Takeda makes patient-level, de-identified data sets and associated documents available for all interventional studies after applicable marketing approvals and commercial availability have been received (or program is completely terminated), an opportunity for the primary publication of the research and final report development has been allowed, and other criteria have been met as set forth in Takeda's Data Sharing Policy (see www.TakedaClinicalTrials.com for details). To obtain access, researchers must submit a legitimate academic research proposal for adjudication by an independent review panel, who will review the scientific merit of the research and the requestor's qualifications and conflict of interest that can result in potential bias. Once approved, qualified researchers who sign a data sharing agreement are provided access to these data in a secure research environment.

Studies a U.S. FDA-regulated Drug Product:

No

Studies a U.S. FDA-regulated Device Product:

No

Keywords provided by Takeda:

Drug Therapy

Additional relevant MeSH terms:

Intestinal Diseases

Inflammatory Bowel Diseases

Gastrointestinal Diseases

Digestive System Diseases

Gastroenteritis