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Trial record **1 of 1** for: nct01561313

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Crossover Study of Safety and Tolerability of Two Formulations of Adalimumab.

This study has been completed.

Sponsor:
AbbVie (prior sponsor, Abbott)

Information provided by (Responsible Party):
AbbVie (AbbVie (prior sponsor, Abbott))

ClinicalTrials.gov Identifier:
NCT01561313

First received: March 21, 2012
Last updated: January 23, 2014
Last verified: January 2014
History of Changes

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Purpose

This study will compare injection site pain levels between current Humira® formulation versus a new formulation of Humira in patients with Rheumatoid Arthritis (RA), who are either currently on a stable dose (minimum six consecutive doses) of on-label Humira or biological naïve who will be prescribed on-label Humira as treatment for their Rheumatoid Arthritis. The study is being conducted in two countries, Belgium (3 sites) and the Czech Republic (3 sites).

Condition	Intervention	Phase
Rheumatoid Arthritis	Biological: Adalimumab	Phase 2

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Safety/Efficacy Study
Intervention Model: Crossover Assignment
Masking: Single Blind (Subject)
Primary Purpose: Treatment

Official Title: A Multicenter, Randomized, Single-Blind Crossover Study of the Safety and Tolerability of Two Adalimumab Formulations in Adult Subjects With Rheumatoid Arthritis.

Resource links provided by NLM:

Genetics Home Reference related topics: rheumatoid arthritis

MedlinePlus related topics: Arthritis Rheumatoid Arthritis

Drug Information available for: Adalimumab

U.S. FDA Resources

Further study details as provided by AbbVie:

Primary Outcome Measures:

- Mean Injection Site Pain on a Visual Analogue Scale (VAS) [Time Frame: Immediately after injection] [Designated as safety issue: Yes]
  The primary response variable is participant's immediate pain of injection on a visual analogue scale (VAS) of 0 to 10 (cm), with 0 representing no pain and 10 representing the worst possible pain.

Secondary Outcome Measures:

- Mean Injection Site Pain on a Visual Analogue Scale (VAS) [Time Frame: 15 minutes post injection] [Designated as safety issue: Yes]

The secondary response variable is participant's pain of injection on a visual analogue scale (VAS) of 0 to 10 (cm) recorded 15 minutes after the injection, with 0 representing no pain and 10 representing the worst possible pain.

- Percentage of Participants With no Hemorrhage/Petechiae in the Draize Scale [Time Frame: 10 minutes and 30 minutes after injection] [Designated as safety issue: No]

  Hemorrhage/petechiae (bleeding/spots of bleeding underneath the skin) was assessed.

- Percentage of Participants With no Erythema in the Draize Scale [Time Frame: 10 minutes and 30 minutes after injection] [Designated as safety issue: No]

  Erythema (redness) was assessed.

- Percentage of Participants With no Edema in the Draize Scale [Time Frame: 10 minutes and 30 minutes after injection] [Designated as safety issue: No]

  Edema (swelling) was assessed.

- Percentage of Participants With no Pruritus in the Draize Scale [Time Frame: 10 minutes and 30 minutes after injection] [Designated as safety issue: No]

  Pruritus (itching) was assessed.

- Number of Participants With Adverse Events (AEs) [Time Frame: Adverse events were collected from the time of study drug administration until 70 days following discontinuation of study drug. Serious Adverse Events were collected from the time the participant signed the informed consent.] [Designated as safety issue: Yes]

  An AE was defined as any untoward medical occurrence in a patient or clinical investigation participant administered a pharmaceutical product and which did not necessarily have a causal relationship with this treatment.

Enrollment:	64
Study Start Date:	March 2012
Study Completion Date:	November 2012
Primary Completion Date:	November 2012 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Active Comparator: Current formulation adalimumab One dose with 40 mg of current formulation of adalimumab in a pre-filled syringe	Biological: Adalimumab Subcutaneously 40 mg every other week (EOW) or every week (EW) (as dosing requires) Other Names: • Humira • ABT-D2E7
Experimental: New formulation of adalimumab One dose with 40 mg of new formulation of adalimumab in a pre-filled syringe	Biological: Adalimumab Subcutaneously 40 mg every other week (EOW) or every week (EW) (as dosing requires) Other Names: • Humira • ABT-D2E7

Detailed Description:
64 participants were randomized, 63 received at least one dose of the study drug, and 62 participants were analyzed for injection site-related pain. 63 participants were analyzed for other safety analyses. Two participants, who were randomized to the Current formulation adalimumab/New formulation of adalimumab arm of the study were excluded from the analysis of injection site-related pain. One participant received one dose of study drug and discontinued because of an adverse event, while the other discontinued before receiving any study drug.

Eligibility

Ages Eligible for Study:	18 Years and older
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Male or female subject age 18 years or older, who requires Humira 40 mg SC every other week (eow) or every week (ew) for the treatment of rheumatoid arthritis, in accordance with the local Humira label.
- Subject must be a current, on-label user of Humira who rates his/her average Humira injection site related pain as at least 3 cm on a pain Visual Analogue Scale and has had at least 6 consecutive doses of Humira prior to Screening, or a biologic naïve subject who requires initiation of on-label treatment with Humira.
- Subject has diagnosis of rheumatoid arthritis (RA) as defined by the 1987 revised ACR classification criteria or the ACR/EULAR 2010 criteria,
- Female subjects are either not of childbearing potential, defined as postmenopausal for at least 1 year or surgically sterile (bilateral tubal ligation, bilateral oophorectomy and/or hysterectomy), or are practicing at least one method of birth control throughout the study and for at least 70 days after the last dose of study drug.
- All female subjects of childbearing potential must have a negative test for pregnancy on a serum sample at Screening and prior to study drug dosing on a urine sample obtained at Visit 1.

Exclusion Criteria:

- Subject has been treated with any investigational drug of a chemical or biologic nature within a minimum of 30 days or 5 half-lives (whichever is longer) of the drug prior to Visit 1.
- Any infection(s) requiring treatment with intravenous (IV) anti-infectives within 30 days prior to Visit 1 or oral anti-infectives within 14 days prior to Visit 1.
- Prior exposure to natalizumab (Tysabri®) or efalizumab (Raptiva®).
- Known hypersensitivity to adalimumab or its excipients.
- History of demyelinating disease (including myelitis) or neurologic symptoms suggestive of demyelinating disease.

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: NCT01561313

Locations

Belgium

Site Reference ID/Investigator# 63357
Genk, Belgium, 3600

Site Reference ID/Investigator# 63359
Ghent, Belgium, 9000

Site Reference ID/Investigator# 63360
Ghent, Belgium, 9000

Czech Republic

Site Reference ID/Investigator# 63363
Brno, Czech Republic, 63800

Site Reference ID/Investigator# 63362
Prague 2, Czech Republic, 128 50

Site Reference ID/Investigator# 63361
Uherske Hradiste, Czech Republic, 686 01

Sponsors and Collaborators

AbbVie (prior sponsor, Abbott)

Investigators

Study Director: Andrew Payne, PhD AbbVie

More Information

Additional Information:

This clinical study may be evaluating a usage that is not currently FDA-approved. Please see US prescribing information for approved uses.

No publications provided

Responsible Party:	AbbVie (AbbVie (prior sponsor, Abbott))
ClinicalTrials.gov Identifier:	NCT01561313 History of Changes
Other Study ID Numbers:	M12-783 2011-002275-41
Study First Received:	March 21, 2012
Results First Received:	November 8, 2013
Last Updated:	January 23, 2014
Health Authority:	Belgium: Federal Agency for Medicines and Health Products, FAMHP Belgium: Ethics Committee Belgium: Federal Agency for Medicinal Products and Health Products Belgium: Institutional Review Board Belgium: Ministry of Social Affairs, Public Health and the Environment Belgium: The Federal Public Service (FPS) Health, Food Chain Safety and Environment Czech Republic: Ethics Committee Czech Republic: State Institute for Drug Control

Keywords provided by AbbVie:
On label Humira users
Pain
Rheumatoid Arthritis,

Additional relevant MeSH terms:

Arthritis	Rheumatic Diseases
Arthritis, Rheumatoid	Adalimumab
Autoimmune Diseases	Anti-Inflammatory Agents
Connective Tissue Diseases	Antirheumatic Agents
Immune System Diseases	Pharmacologic Actions
Joint Diseases	Therapeutic Uses
Musculoskeletal Diseases	

ClinicalTrials.gov processed this record on March 09, 2016