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Trial record **1 of 1** for: NCT01502423

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A Crossover Study of the 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:
NCT01502423

First received: December 1, 2011
Last updated: January 23, 2014
Last verified: January 2014
History of Changes

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Results First Received: November 7, 2013

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

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations
No text entered.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
One participant, who was randomized to the New formulation of adalimumab/Current formulation adalimumab arm, discontinued before receiving any study drug.

Reporting Groups

	Description
Current Formulation Adalimumab/New Formulation of Adalimumab	First dose with 40 mg of current formulation of adalimumab in a pre-filled syringe and second dose with 40 mg of new formulation of adalimumab in a pre-filled syringe.
New Formulation of Adalimumab/Current Formulation Adalimumab	First dose with 40 mg of new formulation of adalimumab in a pre-filled syringe and second dose with 40 mg of current formulation of adalimumab in a pre-filled syringe.

Participant Flow: Overall Study

	Current Formulation Adalimumab/New Formulation of	New Formulation of Adalimumab/Current Formulation

	Adalimumab	Adalimumab
STARTED	**31**	**30**
COMPLETED	**31**	**29**
NOT COMPLETED	**0**	**1**
Withdrawal by Subject	**0**	**1**

Baseline Characteristics

Hide Baseline Characteristics

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All analyses were based on the cITT population, which included all subjects who were randomized and completed both periods and received study drug in both periods of the study (N = 60).

Reporting Groups

	Description
Current Formulation Adalimumab/New Formulation of Adalimumab	First dose with 40 mg of current formulation of adalimumab in a pre-filled syringe and second dose with 40 mg of new formulation of adalimumab in a pre-filled syringe.
New Formulation of Adalimumab/Current Formulation Adalimumab	First dose with 40 mg of new formulation of adalimumab in a pre-filled syringe and second dose with 40 mg of current formulation of adalimumab in a pre-filled syringe.
Total	Total of all reporting groups

Baseline Measures

	Current Formulation Adalimumab/New Formulation of Adalimumab	New Formulation of Adalimumab/Current Formulation Adalimumab	Total
Number of Participants [units: participants]	**31**	**29**	**60**
Age [units: years] Mean (Standard Deviation)	**58.3 (11.56)**	**54.4 (14.11)**	**56.4 (12.90)**
Gender [units: participants]			
Female	**24**	**23**	**47**
Male	**7**	**6**	**13**

Outcome Measures

Show All Outcome Measures

1. Primary: Mean Injection Site Pain on a Visual Analogue Scale (VAS) [Time Frame: Immediately after injection.]

Hide Outcome Measure 1

Measure Type	Primary

Measure Title	Mean Injection Site Pain on a Visual Analogue Scale (VAS)
Measure Description	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.
Time Frame	Immediately after injection.
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
Current Formulation Adalimumab	One dose with 40 mg of current formulation of adalimumab in a pre-filled syringe
New Formulation of Adalimumab	One dose with 40 mg of new formulation of adalimumab in a pre-filled syringe

Measured Values

	Current Formulation Adalimumab	**New Formulation of Adalimumab**
Number of Participants Analyzed [units: participants]	**60**	**60**
Mean Injection Site Pain on a Visual Analogue Scale (VAS) [units: cm] Mean (Standard Deviation)	**4.2 (2.72)**	**0.9 (1.44)**

No statistical analysis provided for Mean Injection Site Pain on a Visual Analogue Scale (VAS)

2. Secondary: Mean Injection Site Pain on a Visual Analogue Scale (VAS) [Time Frame: 15 minutes post injection]

Hide Outcome Measure 2

Measure Type	Secondary
Measure Title	Mean Injection Site Pain on a Visual Analogue Scale (VAS)
Measure Description	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.
Time Frame	15 minutes post injection
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
Current Formulation Adalimumab	One dose with 40 mg of current formulation of adalimumab in a pre-filled syringe
New Formulation of Adalimumab	One dose with 40 mg of new formulation of adalimumab in a pre-filled syringe

Measured Values

	Current Formulation Adalimumab	New Formulation of Adalimumab
Number of Participants Analyzed [units: participants]	**60**	**60**
Mean Injection Site Pain on a Visual Analogue Scale (VAS) [units: cm] Mean (Standard Deviation)	**1.0 (1.61)**	**0.4 (1.08)**

No statistical analysis provided for Mean Injection Site Pain on a Visual Analogue Scale (VAS)

3. Secondary: Percentage of Participants With no Hemorrhage/Petechiae in the Draize Scale [Time Frame: 10 minutes and 30 minutes after injection]

Hide Outcome Measure 3

Measure Type	Secondary
Measure Title	Percentage of Participants With no Hemorrhage/Petechiae in the Draize Scale
Measure Description	Hemorrhage/petechiae (bleeding/spots of bleeding underneath the skin) was assessed.
Time Frame	10 minutes and 30 minutes after injection
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
Current Formulation Adalimumab	One dose with 40 mg of current formulation of adalimumab in a pre-filled syringe
New Formulation of Adalimumab	One dose with 40 mg of new formulation of adalimumab in a pre-filled syringe

Measured Values

	Current Formulation Adalimumab	New Formulation of Adalimumab
Number of Participants Analyzed [units: participants]	**60**	**60**
Percentage of Participants With no Hemorrhage/Petechiae in the Draize Scale [units: Percentage of Participants]		
10 minutes	**80**	**90**
30 minutes	**81.7**	**91.7**

No statistical analysis provided for Percentage of Participants With no Hemorrhage/Petechiae in the Draize Scale

4. Secondary: Percentage of Participants With no Erythema in the Draize Scale [Time Frame: 10 minutes and 30 minutes after injection]

Hide Outcome Measure 4

Measure Type	Secondary
Measure Title	Percentage of Participants With no Erythema in the Draize Scale

Measure Description	Erythema (redness) was assessed.
Time Frame	10 minutes and 30 minutes after injection
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
Current Formulation Adalimumab	One dose with 40 mg of current formulation of adalimumab in a pre-filled syringe
New Formulation of Adalimumab	One dose with 40 mg of new formulation of adalimumab in a pre-filled syringe

Measured Values

	Current Formulation Adalimumab	**New Formulation of Adalimumab**
Number of Participants Analyzed [units: participants]	**60**	**60**
Percentage of Participants With no Erythema in the Draize Scale [units: Percentage of Participants]		
10 minutes	**50**	**63.3**
30 minutes	**60**	**75**

No statistical analysis provided for Percentage of Participants With no Erythema in the Draize Scale

5. Secondary: Percentage of Participants With no Edema in the Draize Scale [Time Frame: 10 minutes and 30 minutes after injection]

Hide Outcome Measure 5

Measure Type	Secondary
Measure Title	Percentage of Participants With no Edema in the Draize Scale
Measure Description	Edema (swelling) was assessed.
Time Frame	10 minutes and 30 minutes after injection
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
Current Formulation Adalimumab	One dose with 40 mg of current formulation of adalimumab in a pre-filled syringe
New Formulation of Adalimumab	One dose with 40 mg of new formulation of adalimumab in a pre-filled syringe

Measured Values

	Current Formulation Adalimumab	**New Formulation of Adalimumab**

Number of Participants Analyzed [units: participants]	**60**	**60**
Percentage of Participants With no Edema in the Draize Scale [units: Percentage of Participants]		
10 minutes	**90**	**93.3**
30 minutes	**91.7**	**95**

No statistical analysis provided for Percentage of Participants With no Edema in the Draize Scale

6. Secondary: Percentage of Participants With no Pruritus in the Draize Scale [Time Frame: 10 minutes and 30 minutes after injection]

Hide Outcome Measure 6

Measure Type	Secondary
Measure Title	Percentage of Participants With no Pruritus in the Draize Scale
Measure Description	Pruritus (itching) was assessed.
Time Frame	10 minutes and 30 minutes after injection
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
Current Formulation Adalimumab	One dose with 40 mg of current formulation of adalimumab in a pre-filled syringe
New Formulation of Adalimumab	One dose with 40 mg of new formulation of adalimumab in a pre-filled syringe

Measured Values

	Current Formulation Adalimumab	**New Formulation of Adalimumab**
Number of Participants Analyzed [units: participants]	**60**	**60**
Percentage of Participants With no Pruritus in the Draize Scale [units: Percentage of Participants]		
10 minutes	**98.3**	**95**
30 minutes	**96.7**	**96.7**

No statistical analysis provided for Percentage of Participants With no Pruritus in the Draize Scale

7. Secondary: 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 that participant signed the informed consent.]

Hide Outcome Measure 7

Measure Type	Secondary
Measure Title	Number of Participants With Adverse Events (AEs)
Measure Description	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.
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 that participant signed the informed consent.
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
Current Formulation Adalimumab	One dose with 40 mg of current formulation of adalimumab in a pre-filled syringe
New Formulation of Adalimumab	One dose with 40 mg of new formulation of adalimumab in a pre-filled syringe

Measured Values

	Current Formulation Adalimumab	**New Formulation of Adalimumab**
Number of Participants Analyzed [units: participants]	**60**	**60**
Number of Participants With Adverse Events (AEs) [units: participants]	**8**	**4**

No statistical analysis provided for Number of Participants With Adverse Events (AEs)

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	Adverse events were collected from the time of study drug administration until 70 days following discontinuation of study drug. In addition, SAEs were collected from the time the participant signed the study-specific informed consent.
Additional Description	No text entered.

Reporting Groups

	Description
Current Formulation Adalimumab	One dose with 40 mg of current formulation of adalimumab in a pre-filled syringe
New Formulation of Adalimumab	One dose with 40 mg of new formulation of adalimumab in a pre-filled syringe

Serious Adverse Events

	Current Formulation Adalimumab	**New Formulation of Adalimumab**
Total, serious adverse events		
# participants affected / at risk	**0/60 (0.00%)**	**0/60 (0.00%)**

Other Adverse Events

Hide Other Adverse Events

Time Frame	Adverse events were collected from the time of study drug administration until 70 days following discontinuation of

	study drug. In addition, SAEs were collected from the time the participant signed the study-specific informed consent.
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	0%

Reporting Groups

	Description
Current Formulation Adalimumab	One dose with 40 mg of current formulation of adalimumab in a pre-filled syringe
New Formulation of Adalimumab	One dose with 40 mg of new formulation of adalimumab in a pre-filled syringe

Other Adverse Events

	Current Formulation Adalimumab	New Formulation of Adalimumab
Total, other (not including serious) adverse events		
# participants affected / at risk	**8/60 (13.33%)**	**4/60 (6.67%)**
General disorders		
CYST [*1]		
# participants affected / at risk	**1/60 (1.67%)**	**0/60 (0.00%)**
INJECTION SITE PRURITUS [*1]		
# participants affected / at risk	**0/60 (0.00%)**	**1/60 (1.67%)**
INJECTION SITE REACTION [*1]		
# participants affected / at risk	**0/60 (0.00%)**	**1/60 (1.67%)**
Infections and infestations		
LOWER RESPIRATORY TRACT INFECTION [*1]		
# participants affected / at risk	**1/60 (1.67%)**	**0/60 (0.00%)**
RESPIRATORY TRACT INFECTION VIRAL [*1]		
# participants affected / at risk	**1/60 (1.67%)**	**0/60 (0.00%)**
UPPER RESPIRATORY TRACT INFECTION [*1]		
# participants affected / at risk	**2/60 (3.33%)**	**1/60 (1.67%)**
URINARY TRACT INFECTION [*1]		
# participants affected / at risk	**2/60 (3.33%)**	**0/60 (0.00%)**
Injury, poisoning and procedural complications		
CONTUSION [*1]		
# participants affected / at risk	**1/60 (1.67%)**	**0/60 (0.00%)**
POST-TRAUMATIC PAIN [*1]		
# participants affected / at risk	**0/60 (0.00%)**	**1/60 (1.67%)**
UPPER LIMB FRACTURE [*1]		
# participants affected / at risk	**1/60 (1.67%)**	**0/60 (0.00%)**
Nervous system disorders		
HEADACHE [*1]		
# participants affected / at risk	**1/60 (1.67%)**	**0/60 (0.00%)**
Psychiatric disorders		
DEPRESSION [*1]		
# participants affected / at risk	**1/60 (1.67%)**	**0/60 (0.00%)**

Respiratory, thoracic and mediastinal disorders		
ASTHMA * 1		
# participants affected / at risk	**1/60 (1.67%)**	**0/60 (0.00%)**
OROPHARYNGEAL PAIN * 1		
# participants affected / at risk	**1/60 (1.67%)**	**0/60 (0.00%)**

* Events were collected by non-systematic assessment
1 Term from vocabulary, MedDRA 15.0

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data
No text entered.

More Information

Hide More Information

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.

There **IS** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

The agreement is:

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed.

☑ **Restriction Description:** AbbVie requests that any investigator or institution that plans on presenting/publishing results disclosure, provide written notification of their request 60 days prior to their presentation/publication. AbbVie requests that no presentation/publication will be instituted until 12 months after a study is completed, or after the first presentation/publication whichever occurs first. A delay may be proposed of a presentation/publication if AbbVie needs to secure patent or proprietary protection.

Results Point of Contact:

Name/Title: Global Medical Services
Organization: AbbVie (prior sponsor, Abbott)
phone: 800-633-9110

No publications provided

Responsible Party:	AbbVie (AbbVie (prior sponsor, Abbott))
ClinicalTrials.gov Identifier:	NCT01502423 History of Changes
Other Study ID Numbers:	M11-964 2011-003953-25 (EudraCT Number)
Study First Received:	December 1, 2011
Results First Received:	November 7, 2013
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Health Authority:	Australia: Department of Health and Ageing Therapeutic Goods Administration

Australia: Human Research Ethics Committee
Germany: Ministry of Health
Germany: Ethics Commission
Canada: Health Canada