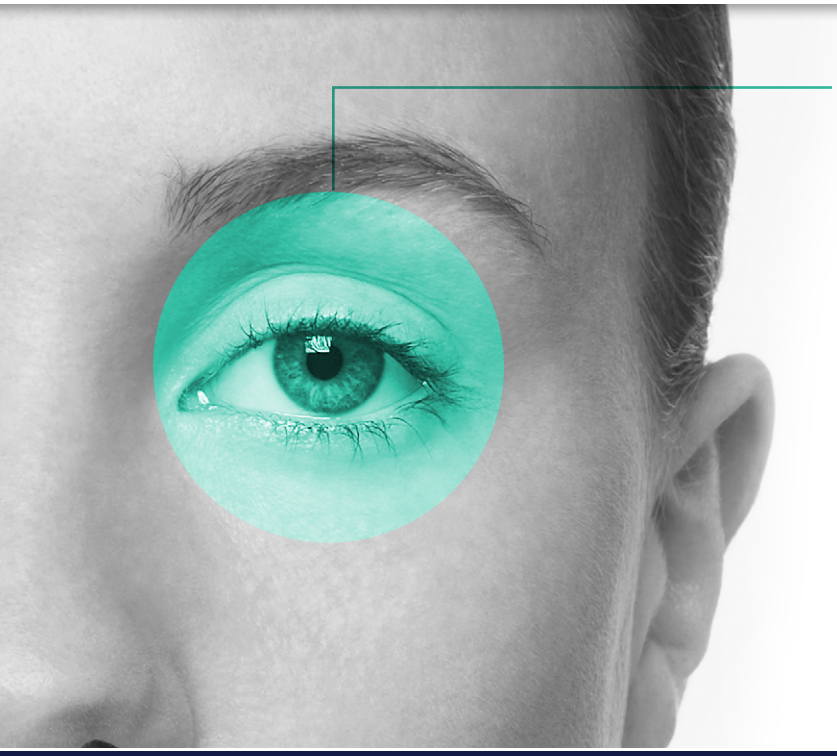
abbvie

Summary of Clinical Trial Results

For Laypersons



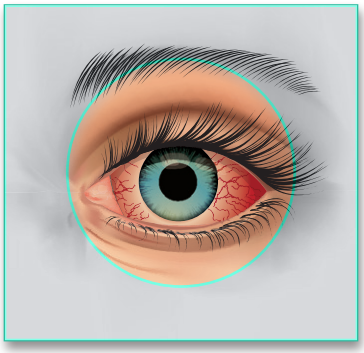
A study to learn how well and safe long-term use of a medicine called adalimumab works to treat adult patients with non-infectious intermediate uveitis, posterior uveitis, or panuveitis

Overall Summary

- Uveitis is a swelling of the middle layer of the eye called the uvea.
- In this study, the study doctors wanted to find out how well adalimumab would benefit patients with non-infectious intermediate uveitis, posterior uveitis, or panuveitis.
- All patients had taken part in either one of the previous two studies with adalimumab: Study M10-877 or Study M10-880.
- This study was open for participation for about 7 years.
- A dose of 40 mg of adalimumab was given to each patient under the skin every other week.
- A total of 424 adult patients took part in the study. Of these, 56.4% completed taking their medicine and 43.6% did not.
- About 53.3% of patients (226 patients) had a side effect during the study considered possibly related to adalimumab.
- This study took place from December 2010 to May 2018 in 21 countries worldwide.
- The results of this study provided more information about the safe and effective use of long-term adalimumab in patients with uveitis.

1. General information about the study

1.1 What was the main objective of this study?



Researchers are looking for a better way to treat an eye condition called uveitis, which can have multiple causes, including inflammatory diseases. Uveitis is a swelling of the middle layer of the eye called the uvea. The uvea is made of the iris, ciliary body, and choroid. Swelling of the back portion of the eye, including the choroid, is called posterior uveitis; swelling of the middle portion of the eye, including the ciliary body, is called intermediate uveitis; and swelling of the front of the eye, including iris, is called anterior uveitis. Swelling of all three parts of the eye (front, middle, and back) is called panuveitis. Uveitis can lead to loss of eyesight. The current medicines used to treat uveitis sometimes lead to unwanted side effects. Because of this, researchers are looking for different medicines to treat patients.

In this study, the researchers wanted to find out how well long-term use of adalimumab would benefit patients with non-infectious intermediate uveitis, posterior uveitis, or panuveitis. Adalimumab works on part of the immune system and may help treat uveitis. Researchers have tested adalimumab on patients with uveitis in two other studies as well.

Researchers planned this study as a Phase 3 open-label study. Phase 3 studies test potential new treatments in a large number of patients with a condition or disease. In this Phase 3 study, the study doctors looked at the benefits of adalimumab and how safe adalimumab was over a long period of time. Patients who took part in the previous two studies of adalimumab and met study qualification criteria were included in this study. Initially, the study was planned for 78 weeks only, but was extended to avoid leaving patients untreated who had responded well to continue the adalimumab therapy until the drug is approved by their country regulatory authorities. This study was open-label, which means that both patients and study doctors knew which medicine they were taking. The study was open for participation for about 7 years.

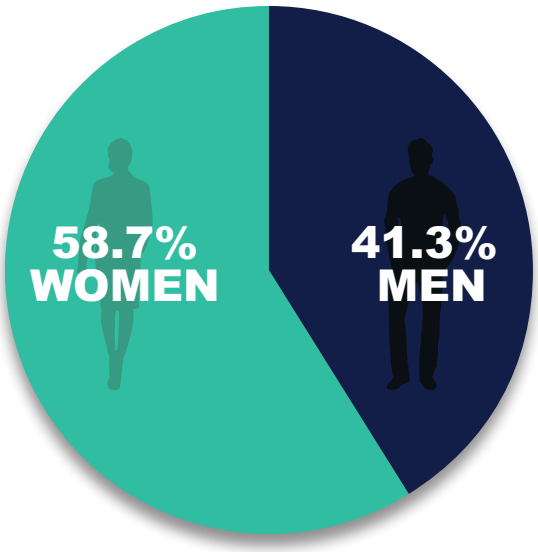
This summary only includes the results from this study, which may be different from the results from other studies.

1.2 When and where did the study take place?

This study took place from December 2010 to May 2018 in the following locations:

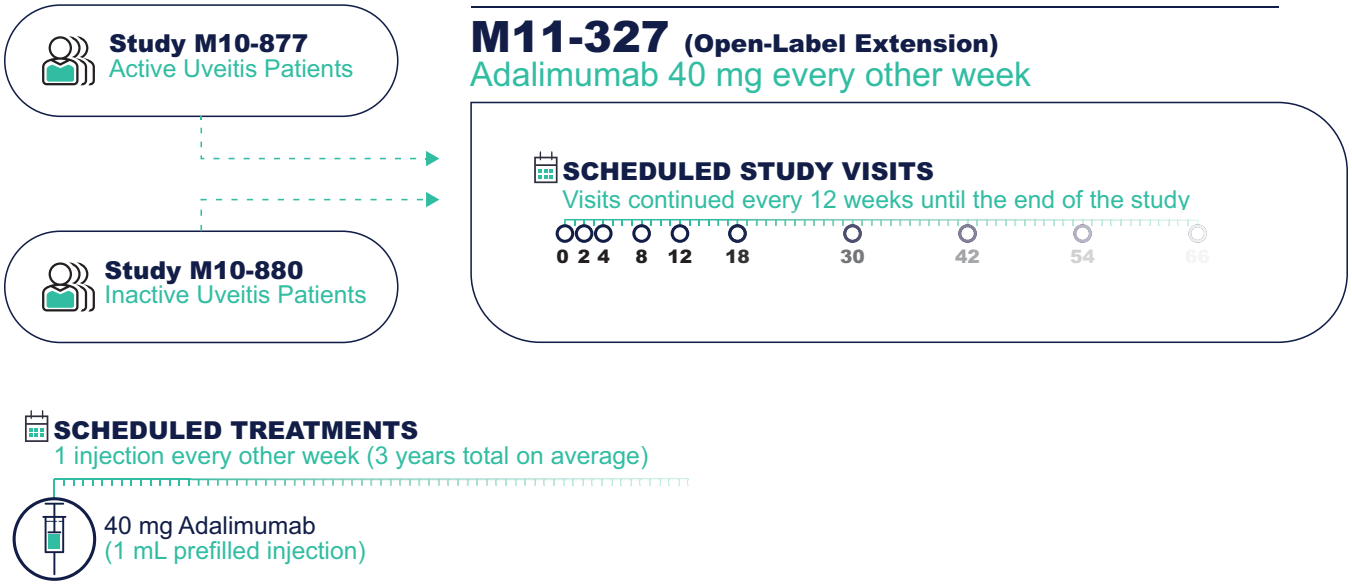
2. What patients were included in this study?

A total of 424 adult patients with intermediate uveitis, posterior uveitis, or panuveitis took part in the study. All patients had taken part in either one of two previous studies of adalimumab: Study M10-877 or Study M10-880. Among the 424 patients, 56.4% completed taking their medicine and 43.6% did not. Patients mostly stopped taking their medicine due to: side effects (18.2%) or adalimumab not working well enough (8.5%). There were more women (58.7%) than men (41.3%) in the study. Study doctors selected only adults in this study. Patients ranged from 19 to 81 years of age.



3. Which medicines were studied?

The medicine used in this study was adalimumab. This medicine is given to patients in 1 milliliter (mL) prefilled injections. Each syringe in the study had 40 milligrams (mg) of adalimumab in it. The injection was given under the skin every other week at about the same time each day it was administered. The diagram below shows how the study was organized.



At the beginning of the study, the study doctors selected patients who met all the requirements of the planned study. Patients were rolled over from either Study M10-880 or Study M10-877. During the treatment period, patients got a 40 mg dose of adalimumab every other week. Scheduled study visits occurred at Weeks 0, 2, 4, 8, 12, 18, and every 12 weeks thereafter until the patient's last visit. During study visits, patients had their blood tested and eyes checked. Doctors checked for the side effects of the drug and how much eye swelling was reduced. The average amount of treatment length was 140.4 weeks, or about 3 years.

During the post-treatment period, patients who received adalimumab were again contacted by study doctors 70 days after getting the last dose of medicine or until the first dose of commercially available drug to provide follow-up information on any new or ongoing side effects.

4. What were the side effects?

Side effects are unwanted medical events that happen during a study. They may or may not be caused by the treatment in the study.

A side effect is serious if it leads to death, is life-threatening, puts a patient in the hospital, keeps a patient in the hospital for a long time, or causes a disability that lasts a long time.

Related side effects are side effects that were at least possibly related to the study drug.

About 23.8% of patients (101 patients) had serious side effects; of these, 6.8% of patients (29 patients) had serious side effects during the study considered possibly related to adalimumab.

About 18.2% of patients (77 patients) stopped taking adalimumab because of side effects; of these, 6.8% of patients (29 patients) stopped taking adalimumab because of side effects considered possibly related to adalimumab. Four patients died during the study; 2 patients died from cancer, 1 patient died from an accident, and 1 patient died from a brain abscess. This brain abscess was the only side effect leading to death considered related to adalimumab.

The table below shows information about the related serious side effects patients had in the study, as well as related side effects patients had that led to the patient stopping adalimumab, and related side effects leading to death.

	OVERALL (n=424 patients)
Number of patients with related serious side effects	29 (6.8% of patients)
Number of patients who stopped taking adalimumab because of related side effects	29 (6.8% of patients)
Number of related side effects leading to death	1 (0.2% of patients)

About 53.3% of patients (226 patients) had a related side effect during the study. The table below shows information about the common related side effects (in at least 10 or more patients) in this study. The most common related side effects were nasopharyngitis (common cold), urinary tract infection, and arthralgia (joint pain).

	OVERALL (n=424 patients)
Number of patients with at least one related side effect	**226 (53.3% of patients)**
Nasopharyngitis (common cold)	37 (8.7% of patients)
Urinary tract infection	24 (5.7% of patients)
Arthralgia (joint pain)	22 (5.2% of patients)
Worsening of uveitis	16 (3.8% of patients)
Fatigue (tiredness)	16 (3.8% of patients)
Bronchitis (lung infection)	15 (3.5% of patients)
Injection site pain	14 (3.3% of patients)
Upper respiratory tract infection	13 (3.1% of patients)
Injection site erythema (redness)	12 (2.8% of patients)
Aspartate aminotransferase increased (liver test abnormaility)	10 (2.4% of patients)
Headache	10 (2.4% of patients)

5. What were the overall results of the study?

The study was completed as planned.

The number and frequency of side effects were similar to those expected in patients in this study. Although 398 of the 424 patients (93.9%) in this study had a side effect, most were mild or moderate. No new safety alerts were seen during this study.

The long-term safety profile of adalimumab in adult patients with non-infectious intermediate uveitis, posterior uveitis, and panuveitis was consistent with the safety profile established in the lead-in studies of adalimumab in uveitis (Studies M10-877 and M10-880).

6. How has the study helped patients and researchers?

This study helped researchers to know how well and safe long-term use of adalimumab works to treat patients with non-infectious intermediate uveitis, posterior uveitis, or panuveitis. Findings from this study may be used in other studies to learn whether patients are helped by adalimumab.

This summary only shows the results from this study, which may be different from the results of other studies. Patients should consult their physicians and/or study doctors with further questions about their individual care and should not make changes in their treatment based on the results of a single study.

7. Are there any plans for future studies?

Currently, there are no plans for future studies in this patient population that include the medicine that was used in this study.

8. Who sponsored this study?

This study was sponsored by AbbVie. This summary was reviewed for readability by a patient advocacy group.



9. Where can I find out more information about this study?

Title of Study	A Multicenter Open-Label Study of the Long-term Safety and Efficacy of the Human Anti-TNF Monoclonal Antibody Adalimumab in Subjects with Non-infectious Intermediate Uveitis, Posterior Uveitis, or Panuveitis
Protocol Number	M11-327
ClinicalTrials.gov	NCT01148225 https://clinicaltrials.gov/ct2/show/study/NCT01148225
EudraCT	2009-016196-29 https://www.clinicaltrialsregister.eu/ctr-search/search?query=2009-016196-29
Study Sponsor	Global Medical Services AbbVie Phone: 800-633-9110 Email: abbvieclinicaltrials@abbvie.com

04 July 2019. This document includes known facts as of the time the document was finalized.

THANK YOU!

Abbvie wants to thank all the participants for their time and effort that went into making this study possible.

Clinical study participants help advance science!