

Please note that this summary only contains information from the full scientific article:

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Using a pre-filled pen to inject an adalimumab biosimilar in people with rheumatoid arthritis



Adalimumab

<ada-LIM-yoo-mab>

Biosimilar

<BY-oh-SIH-mih-ler>

Cytokine

<SY-toh-kine>

Methotrexate

<MEH-thoh-TREK-sayt>

Rheumatoid arthritis

<ROO-muh-TOYD ar-THRY-tis>

Tumor necrosis factor alpha

<TOO-mer neh-KROH-sis FAK-ter AL-fuh>

Date of summary: December 2021

Study number: NCT02480153

Study start date: June 2015

Study end date: December 2017

The full title of this article: Usability study of PF-06410293, an adalimumab biosimilar, by prefilled pen: open-label, single-arm, sub-study of a phase 3 trial in patients with rheumatoid arthritis

The purpose of this plain language summary is to help you to understand the findings from recent research.

- Adalimumab and the adalimumab biosimilar PF-06410293 are approved to treat the condition under study that is discussed in this summary.
- The results of this study may differ from those of other studies. Health professionals should make treatment decisions based on all available evidence not on the results of a single study.

More information can be found in the scientific article of this study, which you can access here: [View Scientific Article](#)

What did this study look at?

- This study looked at how successful people were at injecting the adalimumab biosimilar medicine PF-06410293 using a pre-filled pen, which researchers developed to offer patients more convenience.

What is rheumatoid arthritis?

- Rheumatoid arthritis is an autoimmune disease that causes pain, swelling, and stiffness in people's joints.
 - In people with rheumatoid arthritis, the immune system (the body's own defense cells) attacks the lining that surrounds their own joints.
 - Over time the cartilage and bones in the joint can become damaged. This can make it hard and/or painful to perform daily activities.
 - Cartilage is a type of connective tissue that is flexible.
 - The hands, feet, and wrists are often affected.

How is rheumatoid arthritis treated?

- People with rheumatoid arthritis often take methotrexate, which works by blocking the immune system to reduce inflammation.
- If people's rheumatoid arthritis does not improve with methotrexate, they may also take adalimumab.
 - Adalimumab is a type of biological medicine. It is made from proteins produced naturally by the body.

Additional information

For more information on this study, please visit:

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<https://clinicaltrials.gov/ct2/show/NCT02480153?term=NCT02480153&draw=2&rank=1>

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- Adalimumab works by blocking the activity of a cytokine called tumor necrosis factor alpha (TNF α for short), which is released by immune cells and causes inflammation.
 - Cytokines are proteins that gather immune cells to areas of infection, inflammation, and damage.
- In rheumatoid arthritis, immune cells continue to release TNF α , which causes long-lasting joint inflammation. This can cause painful symptoms.
 - Adalimumab binds to TNF α and stops it from signaling to other immune cells. This reduces inflammation and can reduce painful symptoms.

What are biosimilar medicines?

- Biosimilar medicines are very similar to biological medicines already used by doctors but are less expensive and may increase access to these treatments.
 - Biosimilars are carefully tested to make sure they work as well as biologics and are as safe before they can be used as medicines.
- In a previous study, researchers showed that a biosimilar of adalimumab, known as PF-06410293, was just as safe and effective for treating rheumatoid arthritis.

How do people take adalimumab and PF-06410293?



People take adalimumab and PF-06410293 by injecting it under the skin into their stomach area using a pre-filled syringe, similar to how people with diabetes inject insulin.



Researchers have developed a pre-filled pen to make it easier for people with rheumatoid arthritis to take adalimumab and PF-06410293. Pre-filled pens are single-use and disposable.

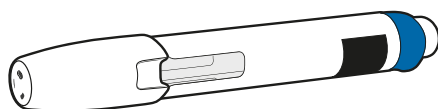


In a previous study, researchers showed that adalimumab or PF-06410293 was as safe and effective at treating rheumatoid arthritis in people who changed from a pre-filled syringe to a pre-filled pen.

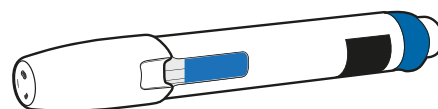
What was the aim of this study?

- In this study, researchers looked at how successful people were at injecting PF-06410293 using a pre-filled pen.
 - Researchers developed pre-filled pens to offer patients more convenience.
- Researchers measured the successful use of the pre-filled pen by calculating the delivery system success rate.
 - People can check a small window on the pre-filled pen to see if they have used the pre-filled pen successfully.
 - If the blue bar has moved across the window, then they successfully used the pre-filled pen.

Before use or unsuccessful use



Successful use



- Users filled out a questionnaire to report if the injection was successful.
- Then, researchers work out the percentage of people who successfully used the pre-filled pen.
- Researchers also looked at the side effects that people with rheumatoid arthritis had when taking ADL-PF using the pre-filled pen.
 - A side effect is something (expected or unexpected) that you feel was caused by a medicine or treatment you take.

Additional information

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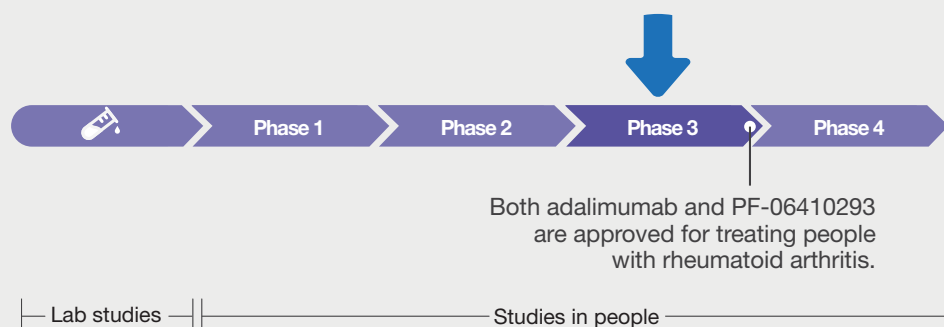
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Where is this study in the drug development timeline?

- This was a sub-study of a larger three-part phase 3 clinical trial that compared the safety and effectiveness of PF-06410293 with adalimumab made in the European Union.
 - A phase 3 clinical trial is a large study (up to thousands of patients) that is long in duration (1–4 years). It looks at how safe a new treatment is and how well it works compared with a standard treatment.
- People could choose to take part in this study if they were already taking part in the larger phase 3 clinical trial.



Who took part in this study and what did they have to do?

Sub-study (weeks 52–66)



PF-06410293
(adalimumab
biosimilar)

- After taking part in a 1-year clinical trial, 50 people with rheumatoid arthritis from the United States, Czech Republic, Lithuania, and Poland volunteered for an additional sub-study.
- People with rheumatoid arthritis or their caregivers had training to help them use the pre-filled pen.
 - They injected 40 mg of PF-06410293 once every other week for 6 weeks using the pre-filled pen.
 - They also took 6 mg to 25 mg of methotrexate each week.
- People used the pre-filled pen at home or at the study center where researchers watched them.

Additional information

For more information on this study, please visit:

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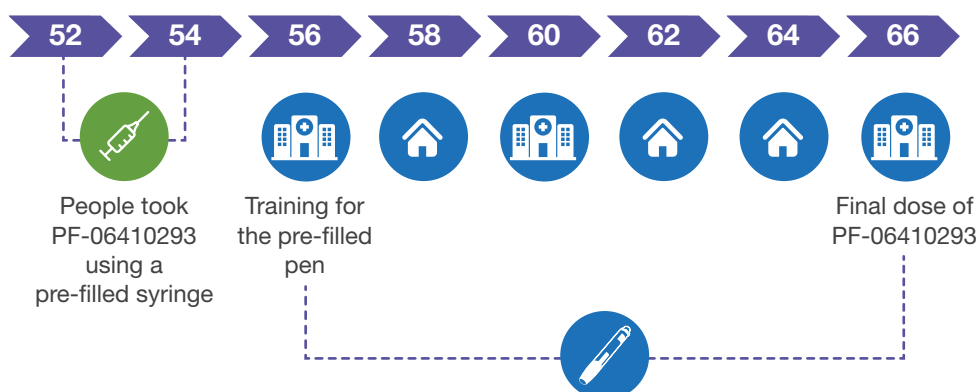
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Weeks





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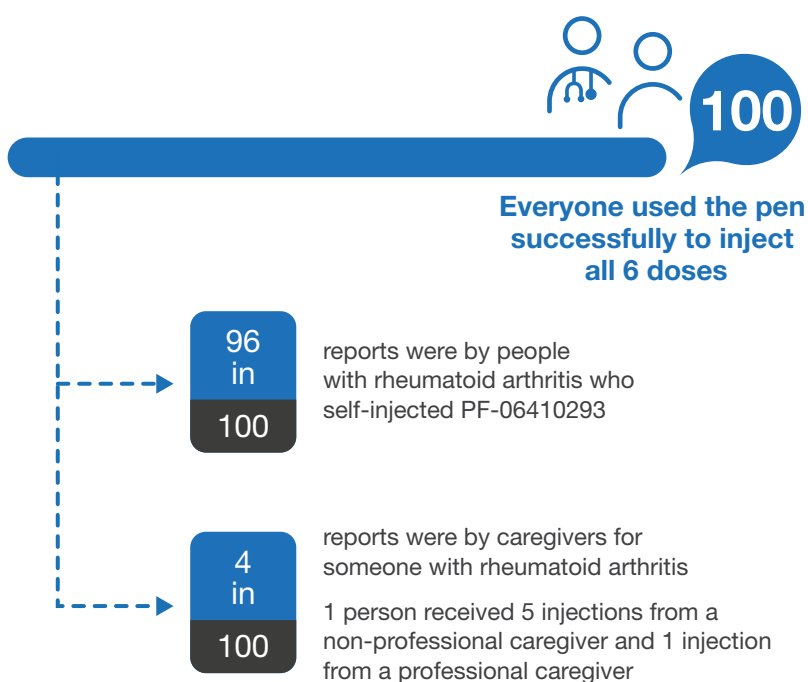
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- On average, the people in this study were 54 years old.
 - Around 70% were female.
 - About 90% were right-handed.
 - On average, they had been living with rheumatoid arthritis for 8 years.
- No one in the study had previously used a pre-filled pen.
- People could continue using the pre-filled pen after the sub-study ended until the end of the phase 3 clinical trial (week 78) if they chose to.
- Researchers monitored people's rheumatoid arthritis during the study.

What were the results of the study?

How successful were people at using the prefilled-pen to inject PF-06410293?



This means that the delivery system success rate score was



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What were the side effects of treatment?

- Researchers looked at how many people had side effects after treatment.
 - A side effect is considered “serious” when it is life-threatening, needs hospital care, or causes lasting problems.
 - The side effects could be for any reason and may not be due to taking the study drug.
 - Researchers looked at side effects in everyone who took at least part of one dose of PF-06410293 using a pre-filled pen.



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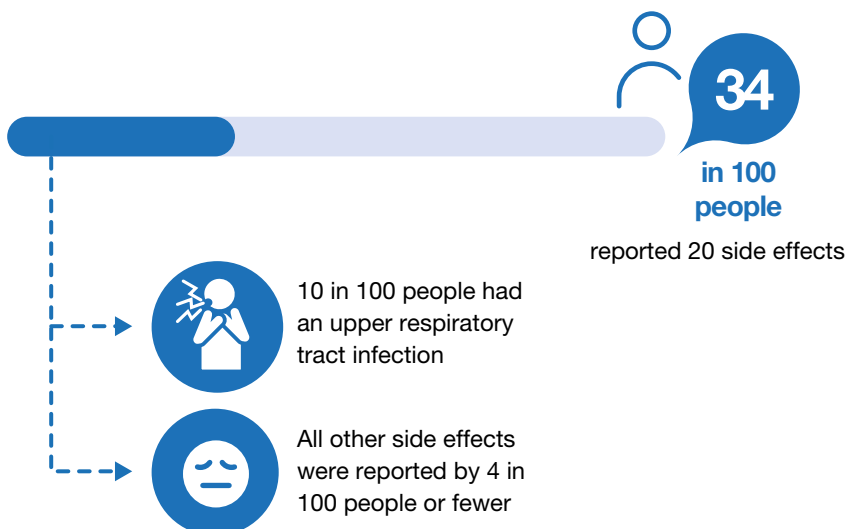
No one died
during this
sub-study



No one had a
reaction at the
site of injection



No one left the study or
stopped treatment
because of side effects



1 person
had tonsillitis



1 person had
rheumatoid arthritis
that worsened



1 person
fractured their
pelvis



Side effects of this sub study were similar to those
reported in the overall clinical trial

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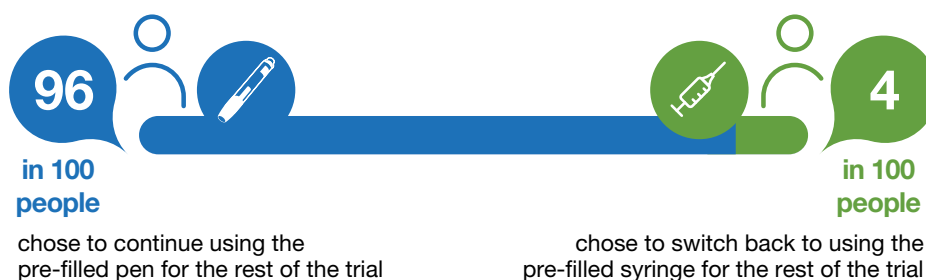
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How many people continued using the pre-filled pen to inject PF-06410293 when the sub-study finished?



More results from this study can be found here: [View Scientific Article](#)



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What were the main conclusions reported by the researchers?

- These findings suggest that people with rheumatoid arthritis and their caregivers can safely and effectively inject PF-06410293 using a pre-filled pen.
- Side effects in people with rheumatoid arthritis using a pre-filled pen to inject PF-06410293 were similar to those in people with rheumatoid arthritis using a pre-filled syringe.
- Most people chose to continue injecting PF-06410293 using a pre-filled pen instead of a pre-filled syringe for the rest of the clinical trial.
- Researchers could not be certain
 - how well people injecting PF-06410293 using a pre-filled pen would have responded without previous experience using a pre-filled syringe.
 - that people with rheumatoid arthritis would receive similar training on how to use the pre-filled pen in a real-world setting.

Are there any plans for further studies?

- There are currently no plans for further studies of PF-06410293 using a pre-filled pen.

Who sponsored this study?

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Pfizer would like to thank all of the people who took part in this study.

Acknowledgements

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