Clinical Study Results

This summary reports the results of only one study. Researchers must look at the results of many types of studies to understand if a study medication works, how it works, and if it is safe to prescribe to patients. The results of this study might be different than the results of other studies that the researchers review.

Sponsor:	Pfizer Inc.
Medicine(s) Studied:	Nyvepria® (pegfilgrastim-apgf)
Protocol Number:	C1221007
Dates of Study:	10 February 2022 to 10 August 2022
Title of this Study:	Pharmacokinetic Study in Healthy Participants to Compare Study Drug (pegfilgrastim-apgf) Given by Two Methods: On-body Injector or Prefilled Syringe (Needle) [A Phase 1, Open-label, Randomized, Single Dose, 2 Way Crossover Study Assessing Pharmacokinetic Comparability of Two PF-06881894 Presentations, On-body Injector and Prefilled Syringe, in Healthy Participants]
Date of this Report:	27 July 2023

– Thank You –

If you participated in this study, Pfizer, the Sponsor, would like to thank you for your participation.

This summary will describe the study results. If you have any questions about the study or the results, please contact the doctor or staff at your study site.

Why was this study done?

What is neutropenia?

A “neutrophil” is a type of white blood cell that fights infections in the body. Certain chemotherapy medicines that are used for treating cancer can cause the number of neutrophils in the body to be too low. This is known as “chemotherapy-induced neutropenia”, or CIN. Patients with CIN are at increased risk for fever and serious infections.

What is Pegfilgrastim-apgf?

Pegfilgrastim-apgf (previously called PF-06881894) is a “granulocyte colony stimulating factor (G-CSF)”. A G-CSF is a type of growth factor that makes the bone marrow produce more white blood cells, including neutrophils.

Pegfilgrastim-apgf is approved for use in the United States when given by needle injection using a prefilled syringe. It is sold as Nyvepria® (Nigh-VEP ree-ah). It is given to decrease the chance of infection in some cancer patients.

What was the purpose of this study?

The purpose of this study was to compare 2 methods of giving pegfilgrastim-apgf by measuring the amount of pegfilgrastim-apgf in the blood at different times.

The 2 methods used in this study were an on-body injector device, or a needle injection using a prefilled syringe. An on-body injector is a device programmed to give an under-the-skin injection automatically and is applied to the skin using an adhesive pad.

Researchers wanted to know:

- **How did Pegfilgrastim-apgf act in the body when it was given by an on-body injector compared to a needle injection using a prefilled syringe?**
- **What medical problems did participants have during the study?**

What happened during the study?

How was the study done?

Researchers tested 2 different methods of giving pegfilgrastim-apgf on a group of healthy participants. They did this to compare how pegfilgrastim-apgf acted in the body when given by on-body injector or by needle injection using a prefilled syringe.

There were 2 treatment periods in the study. Participants received pegfilgrastim-apgf by on-body injector or by needle injection using a prefilled syringe at the start of period 1. They then received pegfilgrastim-apgf using the other method at the start of period 2. Participants were assigned to which method they had first, by chance alone (like the flip of a coin). Each treatment period lasted 28 days, with a gap in between so that there was at least 56 days between the 2 doses of pegfilgrastim-apgf.

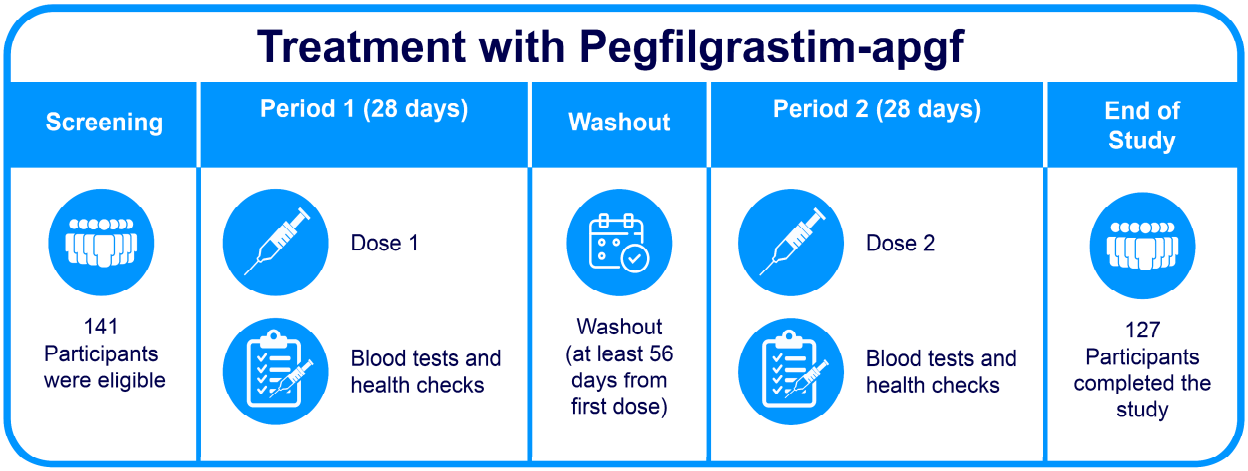
Participants stayed overnight at the clinical research unit for 6 nights in a row each time they were administered pegfilgrastim-apgf. They also had to visit the study site about 20 times in total during the study.

Researchers took samples of blood and urine from participants during the study. They measured the amount of pegfilgrastim-apgf in some of the blood samples. Researchers also checked the participants' health during the study and asked them how they were feeling.

Researchers then compared the results of participants taking pegfilgrastim-apgf when given by on-body injector or by needle injection using a prefilled syringe.

Figure 1 shows what happened during the study.

Figure 1: Study Plan



In period 1, half the participants had pegfilgrastim-apgf using the on-body injector first, and half the participants pegfilgrastim-apgf using needle injection with a prefilled syringe first. The participants swapped methods for period 2. There were 136 participants given pegfilgrastim-apgf using the on-body injector and 136 participants given pegfilgrastim-apgf by needle injection using a prefilled syringe.

Where did this study take place?

The Sponsor ran this study at 4 locations in the US.

When did this study take place?

It began 10 February 2022 and ended 10 August 2022.

Who participated in this study?

The study included healthy participants who met the inclusion/exclusion criteria for things such as age and medical conditions.

- A total of 79 men participated
- A total of 62 women participated
- All participants were between the ages of 19 and 66 years

Of the 141 participants who started the study, 127 participants (90.1%) completed the whole study.

In total, 136 participants received pegfilgrastim-apgf by on-body injector, and 136 participants received pegfilgrastim-apgf by needle injection using a prefilled syringe.

There were 14 participants who left before the study was over by their choice or a doctor decided it was best for them to stop being in the study.

How long did the study last?

Study participants were in the study for approximately 12 weeks. The entire study took 6 months to complete.

When the study ended in August 2022, the Sponsor began reviewing the information collected. The Sponsor then created a report of the results. This is a summary of that report.

What were the results of the study?

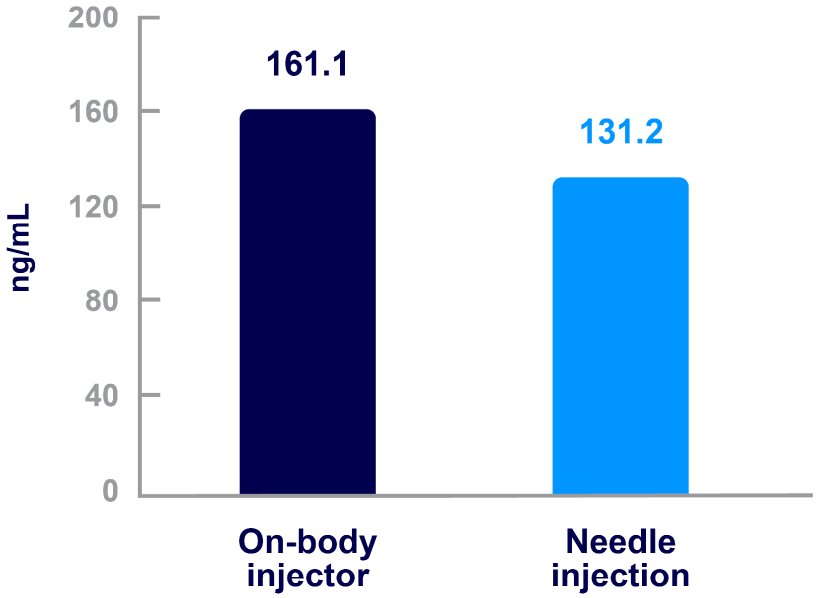
How did Pegfilgrastim-apgf act in the body when it was given by an on-body injector compared to a needle injection using a prefilled syringe?

To see how pegfilgrastim-apgf acted in the body, the researchers measured the amount of pegfilgrastim-apgf in blood samples. These blood samples were collected from participants at different times during the study.

What was the amount of Pegfilgrastim-apgf in the blood after administration by on-body injector, or injection using a prefilled syringe?

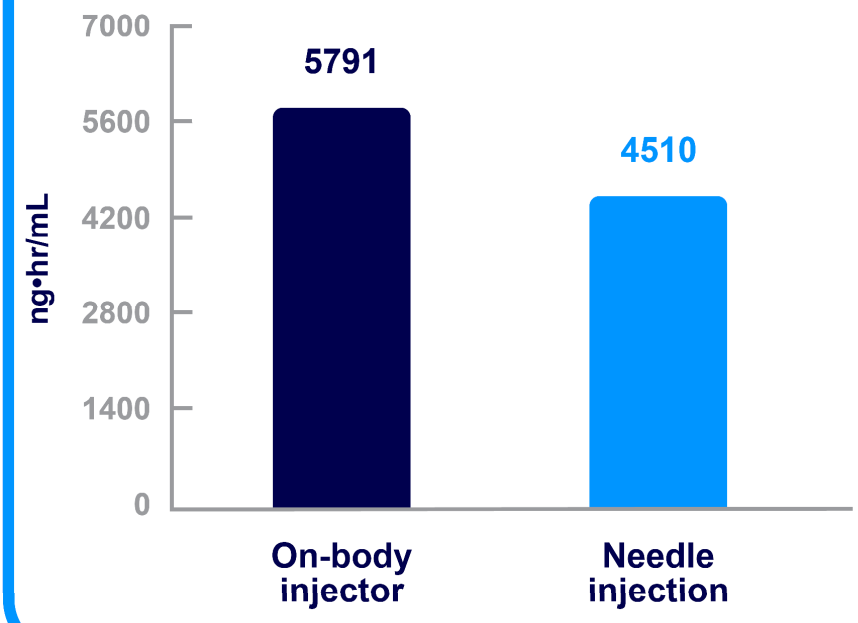
- The highest level of pegfilgrastim-apgf reached in the blood is shown in Figure 2. This is known as C_{max}. The amount of drug in the blood was measured in nanograms per milliliter, also called ng/mL. In this study, the amount of pegfilgrastim-apgf measured in the blood was higher when it was administered by on-body injector than by needle injection using a prefilled syringe.

Figure 2: Pegfilgrastim-apgf C_{max}



- The total amount of pegfilgrastim-apgf from when it was given to the time when the lowest amount was detected in the blood is shown in Figure 3. This is known as AUC_{last}. The ng•hr/mL (nanogram hours per milliliter) is a unit used to measure the total amount of drug over time in the blood. In this study, the total amount of pegfilgrastim-apgf from when it was taken to the time when the lowest amount was detected in the blood was higher when it was administered by on-body injector than by needle injection using a prefilled syringe.

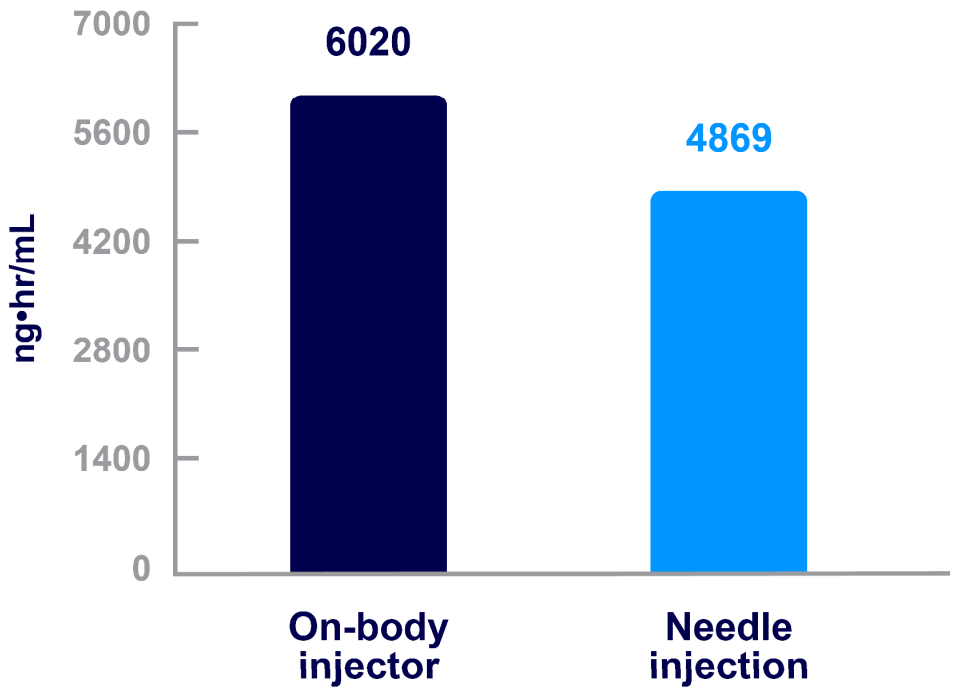
Figure 3: Pegfilgrastim-apgf AUC_{last}



- The estimated total amount of pegfilgrastim-apgf in the blood over time is shown in Figure 4. This is known as AUC_{inf}. In this study, the total amount of pegfilgrastim-apgf in the blood from when it was taken until pegfilgrastim-apgf was removed from the body was

higher when it was administered by on-body injector than by needle injection using a prefilled syringe.

Figure 4: Pegfilgrastim-apgf AUC_{inf}



Based on these results, the researchers have decided that effect of administering pegfilgrastim-apgf by on-body injector and by needle injection using a prefilled syringe was not the same.

This does not mean that everyone in this study had these results. This is a summary of just some of the main results of this study. Other studies may have different results.

What medical problems did participants have during the study?

The researchers recorded any medical problems the participants had during the study. Participants could have had medical problems for reasons not related to the study (for example, caused by an underlying disease or by chance). Or, medical problems could also have been caused by a study treatment or by another medicine the participant was taking. Sometimes the cause of a medical problem is unknown. By comparing medical problems across many treatment groups in many studies, doctors try to understand what effects a study medication might have on a participant.

There were 124 out of 141 (87.9%) participants in this study who had at least 1 medical problem. No participants left the study because of medical problems. The most common medical problems – those reported by more than 5% of participants – are described below.

Below are instructions on how to read Table 1.

Instructions for Understanding Table 1.

- The **1st** column of Table 1 lists medical problems that were commonly reported during the study. All medical problems reported by more than 5% of participants are listed.
- The **2nd** column tells how many of the 136 participants who reported each medical problem after receiving pegfilgrastim-apgf by needle injection using a prefilled syringe. Next to this number is the percentage of the 136 participants who reported the medical problem after receiving pegfilgrastim-apgf by needle injection using a prefilled syringe.

- The **3rd** column tells how many of the 136 participants who reported each medical problem after receiving pegfilgrastim-apgf by on-body injector. Next to this number is the percentage of the 136 participants who reported the medical problem after receiving pegfilgrastim-apgf by on-body injector.
- Using these instructions, you can see that 3 out of the 136 (2.2%) participants reported indigestion after receiving pegfilgrastim-apgf by needle injection using a prefilled syringe. A total of 4 out of the 136 (2.9%) participants reported indigestion after receiving pegfilgrastim-apgf by on-body injector.

Table 1. Commonly reported medical problems by study participants

Medical Problem	Needle injection using a prefilled syringe (136 Participants)	On-body injector (136 Participants)
Indigestion	3 out of 136 participants (2.2%)	4 out of 136 participants (2.9%)
Nausea	9 out of 136 participants (6.6%)	5 out of 136 participants (3.7%)

Table 1. Commonly reported medical problems by study participants		
Medical Problem	**Needle injection using a prefilled syringe (136 Participants)**	**On-body injector (136 Participants)**
Redness at the application site	0	13 out of 136 participants (9.6%)
Redness at the injection site	5 out of 136 participants (3.7%)	2 out of 136 participants (1.5%)
Injection site pain	7 out of 136 participants (5.1%)	0
Positive COVID test	3 out of 136 participants (2.2%)	5 out of 136 participants (3.7%)
Joint pain	3 out of 136 participants (2.2%)	7 out of 136 participants (5.1%)
Back pain	32 out of 136 participants (23.5%)	27 out of 136 participants (19.9%)
Bone or muscle pain	24 out of 136 participants (17.6%)	25 out of 136 participants (18.4%)

Table 1. Commonly reported medical problems by study participants		
Medical Problem	**Needle injection using a prefilled syringe (136 Participants)**	**On-body injector (136 Participants)**
Muscle pain	24 out of 136 participants (17.6%)	23 out of 136 participants (16.9%)
Headache	48 out of 136 participants (35.3%)	51 out of 136 participants (37.5%)

Did study participants have any serious medical problems?

A medical problem is considered “serious” when it is life-threatening, needs hospital care, or causes lasting problems.

No participants had serious medical problems.

There were no participants who died during the study.

Where can I learn more about this study?

If you have questions about the results of your study, please speak with the doctor or staff at your study site.

For more details on your study protocol, please visit:

www.pfizer.com/research/research_clinical_trials/trial_results	Use the protocol number C1221007

The full scientific report of this study is available online at:

www.clinicaltrials.gov	Use the study identifier **NCT05194579**

Please remember that researchers look at the results of many studies to find out which medicines can work and are safe for patients.

Again, if you participated in this study, **thank you** for volunteering. We do research to try to find the best ways to help patients, and you helped us to do that!