Summary of Clinical Study Results

A clinical study of the safety and immune responses of V110 or V114 when given with a COVID vaccine booster dose (V110-911)

This study summary is an overview of the study results. It's intended to help the people who took part in the study understand the results. This study summary:

- Does not replace your healthcare professional's advice;
- Is not a recommendation of how to use the studied medicine*;
- Is not prescribing advice; and
- Does not mean that the studied medicine, or the studied use of the medicine, has been shown to be safe or to work.

You should always talk to a healthcare professional about any treatment decisions. If you participated in this study and have questions about it or the study results, please speak with the study staff.

This study may include treatment plans, medicines, or uses of medicines that have not been approved by your government health authority. The information in this study summary:

- Is from this study only;
- May be different from information in other studies; and
- Does not reflect all information about the studied medicine.

Different studies may be designed to look at different questions or may reach different results. Researchers must look at results from many types of studies to understand if a studied medicine works for a specific use and to learn about its safety.

When a government health agency approves a new medicine, or a new use of a medicine, this is described in the medicine's approved labeling. If the medicine or use explored in this study gets approved, information from this study may or may not be included in the medicine's approved labeling. Check with your healthcare professional, your country's health agency, or your country's MSD office for any approved labeling for this medicine in your country.

*In this statement, the word "medicine" includes drugs, vaccines or other preventative agents.

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A clinical study of the safety and immune responses of V110 or V114 when given with a COVID vaccine booster dose (V110-911)

Full study title: A Phase 3, Randomized, Double-blind, Placebo-controlled Study to Evaluate the Safety, Tolerability, and Immunogenicity of the Concomitant Administration of Either 23-Valent Pneumococcal Polysaccharide Vaccine or 15-Valent Pneumococcal Conjugate Vaccine with a Booster Dose of SARS-CoV-2 mRNA Vaccine in Healthy Adults 50 Years of Age or Older.

Who sponsored this clinical study?

Merck Sharp & Dohme LLC (Rahway, NJ, USA) sponsored this study.

Protocol number: V110-911

EU Clinical Trial Number: Not applicable

Other identifiers:

EudraCT number: 2021-003414-39
US NCT number: NCT05158140

Date: 28-Feb-2024

Thank you!

Thank you to those who took part in this study and to their families and caregivers. You helped researchers learn more about the study vaccines.

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What is a clinical study?

A clinical study is a type of research designed to learn more about how the body responds to medicines, vaccines, or other treatments.

Researchers look at the results of many clinical studies to understand which treatments work and how they work. It takes lots of people in many clinical studies all around the world to advance medical science. This summary only shows the results from this one clinical study. Other clinical studies may show different results.

What were the goals of this clinical study?

Researchers wanted to learn about the safety of 2 study vaccines, called **V110** (23-Valent Pneumococcal Polysaccharide Vaccine) and **V114** (15-Valent Pneumococcal Conjugate Vaccine), when given alone or with a Moderna **COVID** (coronavirus disease 19) vaccine booster dose. Researchers also wanted to learn if the study vaccines help the body make an immune response in adults 50 years and older. **Immune response** is the body's response to infections and illnesses by making **antibodies** (proteins) that fight against germs.

V110 is a study vaccine designed to help prevent **pneumococcal disease** (**PD**). **V114** is another study vaccine designed to help prevent **invasive pneumococcal disease** (**IPD**). PD and IPD are infections caused by pneumococcal bacteria (germs). These bacteria can have over 100 different strains (called **serotypes**). The V110 vaccine contains small parts of 23 serotypes. The V114 vaccine contains small parts of 15 serotypes. These small parts will not cause an infection but will help the body make antibodies to help fight those serotypes.

The **COVID vaccine** helps prevent severe illness from **SARS-CoV-2 virus** (**COVID**), that most often causes flu- or cold-like symptoms. Most people with COVID have mild symptoms, but some people can have severe illness. After people get the original COVID vaccine, people may receive other doses later on called **boosters**. A booster dose helps protect people because protection from the original vaccine can fade over time.

The main goals of this study were to learn:

- If it is safe to give either V110 or V114 vaccines with the COVID vaccine on the same day or 1 month later
- If people aged 50 years and older tolerate either V110 or V114 vaccines when given together with the COVID vaccine on the same day or 1 month later
- If V110 and V114 vaccines work to make an immune response in the body when given together with the COVID vaccine on the same day or 1 month later
- If there is an immune response to the COVID vaccine when given with V110 or V114 vaccine

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What kind of clinical study was this?

This was a randomized, double-blind, phase 3 study:

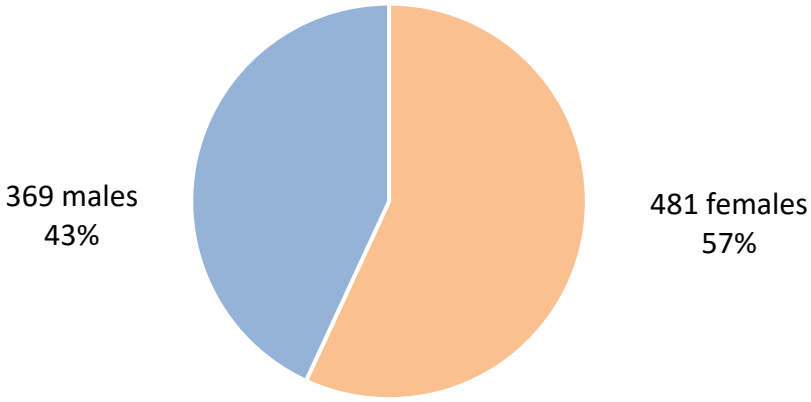
- **Randomized** means that researchers assigned people by chance to a treatment group
- **Double-blind** means neither the people in the study nor the researchers knew which treatment a person received
- A **phase 3** study learns about a study treatment given to a large number of people

When did this clinical study start and end?

This study started in January 2022 and ended in February 2023.

Who took part in this clinical study?

850 people from the United States, including Puerto Rico, were in this study. They were between the ages of 50 to 93 years old. The average age was 60 years old. The graph below shows how many males and females took part:



A person **could** be in this study if they:

- Were healthy
- Were at least 50 years old
- Had received the original COVID vaccine (which was 2 doses of the Moderna COVID vaccine) at least 5 months before joining the study
- Did not have COVID in the past 3 months

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42 people did not finish the study. This table shows the reasons:

Reason people did not finish the study	Number of people
They decided to stop taking part in the study	20
The researchers were unable to contact them	16
They were not given the study vaccine because they were accepted into the study by mistake	5
They died	1

What treatments were studied?

People received an injection (shot) of:

- **Either V110 or V114** – the study vaccines
- **Moderna COVID vaccine** – a booster dose
- **Placebo** – a placebo looks like the study vaccine but has no vaccine in it. Using a placebo helps researchers better understand the effects of a study vaccine.

What happened during this clinical study?

People were assigned by equal chance to one of these groups:

	Treatments they received on Day 1	Treatment they received a month later
Group 1	• V110 • COVID vaccine	Placebo
Group 2	• Placebo • COVID vaccine	V110
Group 3	• V114 • COVID vaccine	Placebo
Group 4	• Placebo • COVID vaccine	V114

People received V110 or V114 and placebo as injections in their left arm. They received the COVID vaccine injection in their right arm. Researchers watched people for 30 minutes after each injection.

During the study, people gave blood samples and had physical examinations. Researchers contacted people up to 5 months after their last dose to check if they had any health problems.

Overall results of this clinical study

Did the vaccines work to make an immune response?

To answer this question, researchers measured the antibody level for each serotype in V110 or V114 in people's blood samples. Researchers also measured the antibody level for COVID. Researchers measured antibody levels 30 days after people received each vaccine.

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Researchers looked at the immune responses of people who received the COVID vaccine and either V110 or V114 on the same day compared to those people who received the COVID vaccine and either V110 or V114 a month apart.

Researchers learned that:

- People's immune responses to V110 were similar when V110 was given on the same day with the COVID vaccine or one month later
- People's immune responses to the COVID vaccine were slightly lower when the COVID vaccine was given on the same day with V110 compared with when the COVID vaccine was given with the placebo
- People's immune responses to V114 were similar when V114 was given on the same day with the COVID vaccine or one month later
- People's immune responses to the COVID vaccine were lower when the COVID vaccine was given on the same day with V114 compared with when the COVID vaccine was given with the placebo

What adverse events were reported?

In this study, researchers wanted to know if certain **adverse events (AEs)** happened after people received any dose of V110 or V114 alone or with the COVID vaccine.

At each visit, researchers asked if the person had certain adverse events. Researchers recorded the number of people who had certain AEs up to 1 week after receiving any vaccine. The certain AEs included:

- Problems (AEs) in the body where the study vaccine was given, including:
  - Redness
  - Swelling
  - Pain or tenderness
  - Under arm swelling or tenderness
- Problems (AEs) somewhere else in the body, including:
  - Headache
  - Feeling weak and tired
  - Muscle aches
  - Joint pain
  - Feeling sick to one's stomach
  - Vomiting
  - Chills

What is an adverse event and adverse reaction?

Adverse events are health problems that happen or worsen during a clinical study. Adverse events **may or may not** be caused by the treatment a person received in a study.

Adverse reactions are adverse events that the researchers believe **could be related to the treatment** a person received in a study.

An adverse event or reaction is **considered serious** when it:

- Is life-threatening
- Causes lasting problems
- Requires hospital care
- Results in death

Researchers also wanted to know if any **serious adverse reactions** happened during the study.

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Number (%) of people who had certain AEs				
	Group 1 V110 and COVID vaccine on Day 1 (Out of 214 people)	**Group 2 COVID vaccine on Day 1 and V110 a month later** (Out of 211 people)	**Group 3 V114 and COVID vaccine on Day 1** (Out of 209 people)	**Group 4 COVID vaccine on Day 1 and V114 a month later** (Out of 208 people)
AE in the body where the study vaccine was given	164 (77%)	162 (77%)	154 (74%)	164 (79%)
AE somewhere else in the body	132 (62%)	123 (58%)	121 (58%)	132 (64%)
Serious AE that researchers believe could be related to the treatment (**adverse reaction**)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

3 people stopped receiving the vaccine due to an AE:

- 1 person in Group 1 (received V110 and COVID vaccine on Day 1) because of a hard lump at the area where they received an injection. This lump was not serious. Researchers believe this AE could be related to the vaccine.
- 2 people in Group 4 (received COVID vaccine on Day 1 and V114 a month later) because of a serious adverse event. One person had cancer of the pancreas. The other person had a heart attack and died. Researchers do not believe these AEs were related to the vaccine given.

What adverse reactions did people have during this study?

In addition to adverse events, researchers also looked at **adverse reactions (serious and non-serious)** that happened during the study. This summary only provides information on the adverse reactions recorded during this study. Other studies may record different adverse reactions.

What serious adverse reactions did people have during this study?

At each visit, researchers asked if the person had any serious adverse reactions.

There were **no serious adverse reactions** reported during the study.

What is an adverse reaction and a serious adverse reaction?

Adverse reactions are health problems that happen or worsen during a study that researchers believe **could be related to the** treatment a person received in a study.

An adverse reaction is **considered serious** when it:

- Is life-threatening
- Causes lasting problems
- Requires hospital care
- Results in death

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What were the most common non-serious adverse reactions?

Most people had a non-serious adverse reaction. The most common non-serious adverse reaction was pain in the body where an injection was given. The table below shows the most common **non-serious adverse reactions** that happened in 10% or more people (10 or more out of 100 people) in any group up to 5 months after the last vaccine.

Non-serious adverse reactions	**Number (%) of people**			
	Group 1 V110 and COVID vaccine on Day 1 (Out of 214 people)	**Group 2 COVID vaccine on Day 1 and V110 a month later** (Out of 211 people)	**Group 3 V114 and COVID vaccine on Day 1** (Out of 209 people)	**Group 4 COVID vaccine on Day 1 and V114 a month later** (Out of 208 people)
Pain in the body where an injection was given	160 (75%)	157 (74%)	148 (71%)	160 (77%)
Feeling weak and tired	82 (38%)	72 (34%)	81 (39%)	96 (46%)
Headache	59 (28%)	70 (33%)	55 (26%)	78 (38%)
Swelling in the body where an injection was given	50 (23%)	56 (27%)	43 (21%)	61 (29%)
Muscle aches or pain	37 (17%)	50 (24%)	44 (21%)	54 (26%)
Enlarged (swollen) lymph nodes. Lymph nodes are small, bean-shaped organs that are part of the body's immune system	37 (17%)	53 (25%)	37 (18%)	53 (26%)
Chills	39 (18%)	35 (17%)	36 (17%)	38 (18%)
Skin redness where an injection was given	40 (19%)	31 (15%)	32 (15%)	36 (17%)
Joint pain	29 (14%)	36 (17%)	34 (16%)	39 (19%)
Feeling sick to the stomach (nausea)	20 (9%)	27 (13%)	18 (9%)	26 (13%)

What did researchers learn from this study?

Researchers learned about the safety and immune response of V110 and V114 when given on the same day or a month after a COVID vaccine. The results from this study may be useful in further developing V110 and V114.

Are there plans for future clinical studies?

Researchers may continue to do studies to learn more about V110 and V114.

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Where can I find more information about this clinical study?

To learn more about this clinical study, visit:

- ClinicalTrials.gov at Study Details | Safety, Tolerability, and Immunogenicity of V110 or V114 Co-administered With a Booster Dose of mRNA-1273 in Healthy Adults (V110-911) | ClinicalTrials.gov

For questions about this summary, contact the clinical study sponsor, Merck, Sharp & Dohme LLC (Rahway, NJ, USA), at: ClinicalTrialsDisclosure@merck.com