Moderna (mRNA-1273)

How is this vaccine given?

This vaccine is given as an injection into the muscle of your upper arm (similar size and location to the flu shot). You need to get two doses, 28 days apart.

How does this vaccine work?

Like all vaccines, this vaccine is designed to mimic a natural viral infection in order to get the body to produce immunity without the risks of natural infection. The vaccine contains a synthetic messenger RNA (mRNA) which encodes the SARS-COV-2 spike glycoprotein (S) antigen encapsulated in lipid nanoparticles. The lipid nanoparticle coat allows the mRNA to enter the host cell and cause it to produce the viral spike glycoprotein (S) antigen. The host's immune system can then recognize and begin to produce antibodies against this viral antigen. The antibodies are protective against future SARS-COV-2 infection. mRNA is broken down rapidly by the host cells through natural processes so this approach has a built in "off-switch" in the body. Because the RNA for only one viral protein is present, the host cell cannot produce infectious virus. **The vaccine cannot cause SARS-COV-2 infection.**

Are there other vaccines that work like this?

There are no other currently FDA approved vaccines that work through this specific mechanism. This vaccine works similarly to the Pfizer COVID vaccine.

What studies have been done to evaluate this vaccine?

Study 101 (125 participants) and Study 201 (600 participants) were performed to test the safety and immunogenicity (ability to make the host produce antibody against the virus) of the vaccine in healthy adults.

Study 301 is an ongoing study with 30,351 adult participants. This study is looking at safety, immunogenicity, and efficacy (are people who've had the vaccine protected against COVID-19 infection compared to those who have not). This is a randomized, placebo-controlled trial occurring in the US.

Is this vaccine safe?

The rate of serious safety events in the study was low (0.5%) and there was no difference noted between the placebo and vaccine groups (0.5% vs 0.6%).

The rate of discontinuations (people not receiving the 2nd dose due to a reaction to the first dose) was low (0.3%) and there was no difference noted between the placebo and vaccine groups (0.3% vs 0.5%).

The follow up in the study (so far) has been three months so we can't exclude the possibility of adverse events that occur more than 3 months after receipt of the vaccine. Given the number of people in the trial we also can't rule out the possibility of adverse events that are less common than ~1/10,000 recipients.

While no vaccine is perfectly safe, the evidence strongly indicates that the vaccine is likely much less risky than the risk of acquiring SARS-COV-2 infection during a pandemic situation.

Does the vaccine work?

Vaccine recipients produced antibody levels higher than those found in persons who had natural illness with SARS-COV-2 and which lasted at least 3 months after receipt of the 2nd dose of vaccine. Vaccine recipients also had strong T-cell responses which typically correlate with protection against viral infection.

When examining new infections with SARS-COV-2 that began at least 14 days after receipt of the 2nd dose of vaccine, 11 vaccine recipients went on to have SARS-COV-2 infection. In comparison, 185 non-vaccine recipients developed infection with SARS-COV-2. The data indicates that the vaccine efficacy is almost certainly somewhere between 89-97% (point estimate 94%). This means a vaccine-recipient's chance of getting SARS-COV-2 infection is reduced by 90% compared to doing nothing.

Vaccine efficacy was similar to the overall group for sub-groups of age, sex, and race/ethnicity. Vaccine efficacy was also similar for those with co-morbidities.

How long does immunity last?

We know it lasts at least 3 months. Data from the ongoing clinical trials will continue to accrue and will be 2-4 months ahead of the first recipients of the vaccine outside of a clinical trial.

What are the common side effects I may experience?

About 85% of participants reported pain at the injection site. Other local reactions included redness, swelling at the injection site, and swollen lymph nodes (about 5-15% each). No participants reported severe local reactions.

Systemic reactions were also generally mild to moderate in severity. Most began 1 or 2 days after receipt of the vaccine and resolved within 1-2 days after they began. Common systemic reactions are summarized below. Systemic reactions were more common after the second dose. In general, both local and systemic reactions were more frequent in younger adults.

Systemic Events within 7 days of Vaccine Receipt 16-55 years				
	Dose 1		**Dose 2**	
Reaction	**Vaccine**	**Placebo**	**Vaccine**	**Placebo**
Fatigue	37%	27%	65%	23%
Headache	33%	27%	59%	23%
Muscle Pain	22%	14%	58%	12%
Chills	8%	6%	44%	6%
Joint Pain	17%	12%	43%	11%
Fever	1%	0.3%	16%	0.3%
Nausea/Vomiting	8%	7%	19%	6%

What if I have a history of severe allergic reaction to other vaccines, foods, or drugs?

There were no immediate allergic reactions to the vaccine reported in the clinical trial. Anaphylaxis (a severe allergic reaction) has been reported in a small number of recipients of the Pfizer COVID vaccine. A history of anaphylaxis or allergy to other drugs, vaccines, or foods does not prevent you from getting the Moderna COVID vaccine. We will observe you for a longer period (30 minutes) after you receive the vaccine if you have a history of anaphylaxis. We are equipped to treat you for anaphylaxis in the unlikely event that it occurs.

What is in the vaccine?

The vaccine contains mRNA and lipid nanoparticles. The vaccine does not contain and is not made using any human cells, viral vectors, preservatives, or adjuvants.

Can I receive the vaccine if I am pregnant?

The vaccine was not studied in pregnant women. There is no scientific data about the safety or effectiveness of this vaccine in pregnant women. Thirteen study participants became pregnant and are being followed. Pregnancy does not prevent you from choosing to get the vaccine. If you are pregnant, we recommend that you discuss the risks and benefits of getting the vaccine with your healthcare provider prior to receiving the vaccination. The Society of Maternal Fetal Medicine has outlined some considerations here: https://s3.amazonaws.com/cdn.smfm.org/media/2641/Provider_Considerations_for_Engaging_in_COVID_Vaccination_Considerations_12-15-20_(final).pdf

Can I receive the vaccine if I am breastfeeding?

This vaccine was not studied in breastfeeding women. Based on our understanding of how the vaccine works, it is believed to be unlikely that vaccine would significantly affect a breastfeeding infant (https://www.infantrisk.com/covid-19-vaccine-pregnancy-and-breastfeeding). However, this remains unproven. Breastfeeding does not prevent you from choosing to receive the vaccine. If you are breastfeeding, we recommend that you discuss the risks and benefits of getting the vaccine with your healthcare provider prior to receiving the vaccination.

Can I receive the vaccine if I am immune compromised or taking immune suppressing medications like steroids?

This vaccine was not studied in these populations. This is not a live vaccine so it should not pose any risk of infection to immune compromised persons. Being immune compromised is not a contraindication to receiving this vaccine. Being immune compromised may reduce the effectiveness of the vaccine. Due to the wide variety of immune compromising medications and conditions, we recommend you discuss your medication and/or condition with your doctor to understand the optimal strategy for receiving your COVID vaccine.