

Plain English Summary

What was the purpose of this study?

This study tested a new experimental COVID-19 vaccine called **NeomiVac**. The main aim was to find out whether NeomiVac is **safe and acceptable** when given as a single injection to healthy adults. The study also looked at how the immune system responded to the vaccine.

Why was this study carried out?

COVID-19 continues to change over time, with new variants appearing. Some newer vaccines are being developed to target these variants more specifically. NeomiVac is an **mRNA vaccine** designed to target the Omicron variant of SARS-CoV-2.

Before any new vaccine can be tested in large numbers of people, early-phase studies are needed to understand safety and side effects.

Who took part?

- **36 healthy adults** aged between **18 and 64 years** took part in the study.
- All participants lived in the UK.
- All had previously received COVID-19 vaccines.
- Around **three-quarters** of participants had previously had COVID-19.
- Everyone who enrolled completed the full study follow-up.

What happened during the study?

This was an early-stage (Phase 1) study carried out at one research centre in Oxford, UK.

Each participant received **one injection** of NeomiVac into a muscle. Different dose levels were tested to help understand safety at increasing amounts:

- 25 micrograms
- 50 micrograms
- 100 micrograms

Participants were followed for around **six months**. During this time, researchers:

- Asked participants about side effects
- Checked their general health
- Took blood samples to monitor safety and immune responses

What were the main findings?

Side effects and safety

- Most side effects were **mild or moderate** and did not last long.
- The most common side effect was **pain where the injection was given**, especially at higher doses.
- Some participants reported **headache, tiredness, muscle aches, or feeling feverish** for a short time.
- No severe allergic reactions linked to the vaccine occurred.
- No participants died during the study.

Blood test findings

- Some participants had **temporary changes in blood test results**, such as small changes in red or white blood cells.
- Most changes were **mild**, caused no symptoms, and returned to normal without treatment.
- One participant had a temporary low potassium level, which resolved and was not thought to be related to the vaccine.
- Mild changes in liver blood tests were seen in a small number of participants and were not considered clinically serious.

What do these results mean?

In this small early-stage study, **NeomiVac was generally safe and tolerated** at all doses tested. The types of side effects seen were similar to those reported with other mRNA COVID-19 vaccines.

This study was **not designed to show whether the vaccine prevents COVID-19**, and it was too small to identify rare side effects. Larger studies would be needed to answer these questions.

What happens next?

The results from this study may help researchers decide whether further studies of NeomiVac should be carried out. Future research would involve more participants and could look at safety in a wider range of people, as well as how well the vaccine works.

Compliance Statement

This lay summary has been prepared in accordance with Health Research Authority guidance on plain English summaries and is intended for a non-specialist public

audience. It provides a balanced and accurate overview of the study purpose, conduct and findings, without overstating benefits or implications.