Tozinameran (Covid-19) Vaccine by Pfizer-BioNtech

Tozinameran vaccine (brand name Comirnaty) is a Covid-19 vaccine produced by Pfizer and BioNtech against Covid-19 virus.

What is Covid-19?

Covid-19 stands for Coronavirus Disease 2019. Coronaviruses are a causation of colds and flu. Scientists say they have identified a new strain of coronavirus and named it after the year it was discovered, 2019, hence the abbreviated Covid-19.

Covid-19 is a respiratory virus that can cause the following symptoms:

A high temperature

A new, continuous cough (three or more coughing episodes in 24 hours or coughing continuously for more than one hour)

Loss or alteration to your sense of smell or taste.

The majority of people who contract Covid-19 will have a mild or moderate illness that requires no treatment.

Those over the age of 70 and with pre-existing conditions such as diabetes, cancer or respiratory disorders are more likely to experience severe effects from coronavirus. One in five over 80 year old's will require hospital treatment and the death rate of coronavirus in that age range is 0.66%.

The Vaccine

Pfizer's Comirnaty vaccine is an mRNA vaccine, not a traditional vaccine with an antigen. Instead of using an antigen, messenger ribonucleic acid vaccines deliver messages contained in the DNA to the rest of the cells. In coronavirus, there are sugar coated spike proteins that enter cells to enable the virus to infect the host. In mRNA vaccines, the RNA carries instructions for the building of these coronavirus spike proteins. Once injected, the vaccine enters the cells and the body begins to produce the coronavirus spike protein as instructed. This induces an immune response and if in the future the vaccinated person comes into contact with coronavirus, antibodies will be produced.

An advantage to this type of vaccine is that no actual antigen is required for injection. Traditional antigen vaccines often garner a poor response and may be injurious (for example, like the whole cell pertussis vaccine which was later scrapped in favour of an acellular vaccine, reported to have fewer side-effects).

However, this type of vaccine technology is brand new and has never been done before so its long-term effects are unknown. It is V.A.N UK's opinion that covid vaccinations are in fact, gene therapy, rather than vaccination. Journalist George Leon wrote in the Press and Journal newspaper that genetically engineered vaccines would 'save millions of lives' and this was the reason why people should all embrace genetic engineering.

Composition of the Vaccine

1 vial (0.45 mL) contains 5 doses of 30 micrograms of BNT162b2 RNA (embedded in lipid nanoparticles). COVID-19 mRNA Vaccine BNT162b2 is highly purified single-stranded, 5'-capped messenger RNA (mRNA) produced by cell-free in vitro

transcription from the corresponding DNA templates, encoding the viral spike (S) protein of SARS-CoV-2.

Excipients are polyethylene glycol/macrogol (PEG) as part of ALC-0159. ALC-0315 = (4-hydroxybutyl) azanediyl)bis (hexane-6,1-diyl)bis(2-hexyldecanoate), ALC-0159 = 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 1,2-Distearoyl-sn-glycero-3-phosphocholine, cholesterol, potassium chloride, potassium dihydrogen phosphate, sodium chloride, disodium hydrogen phosphate dihydrate, sucrose, water for injections.

Safety Trials

Safety trials are still being undertaken for this vaccine. In trial C4951001, phase one included two groups of people, both male and female aged between 18-55 and 65-85 years of age. In phase 2 and 3, people aged over 12 years were used. All participants were healthy or had stable pre-existing conditions.

People with medical conditions requiring treatment, immunosuppression, or a history of severe adverse reaction to any vaccination were excluded from the study. Anyone with a bleeding disorder and people who had had a blood transfusion up to 60 days prior to the study were excluded.

Pregnant or breastfeeding women were excluded and have not been studied in any trial.

The trial was observer blinded but not blinded from staff administering the vaccine or the placebo. The placebo was, unusually for a vaccine trial, saline. (Other vaccines or aluminium are usually used as placebos in studies of vaccines).

A total of 9318 males and 8924 females received the vaccine. Of these, 46 were children aged 12-15 years, 66 were teens aged 16 to 17 years, 14,216 were aged 16-64 years, 3,176 were aged 65-74 years, 804 were 75+, 799 were 75-85 years and 5 were 85 or over.

Efficacy

The study reported a 95.0% efficacy rate in preventing Covid-19. There were 9 cases of covid-19 in the vaccine group after dose 2 and 169 cases in the placebo group. However, they only counted Covid cases that occurred at least 7 days after the first and second doses and did not count cases occurring within the first week of vaccination. It was also up to the medical staff as to whether they performed covid tests on symptomatic individuals which could have skewed the results.

As Peter Doshi pointed out in the British Medical Journal, staff were not required to give all symptomatic participants a covid test. They were aware who had received the vaccine and who had received the placebo so they may have given the placebo group more tests than the vaccine group on the assumption that they are more likely to get covid-19. This is called ascertainment bias.

A good quality trial would have insisted upon testing for both groups.

In addition, the symptoms of covid are similar to vaccine side-effects (headache, fever, chills) so vaccine recipients who displayed those symptoms may have been passed off as having vaccine side-effects rather than covid-19.

No long term study has ever been undertaken to determine efficacy and whether these results mean a vaccinated person will not contract or pass on covid-19.

The New England Journal of Medicine stated:

'Comprehensive information on the duration of protection remain to be determined....assessment of long-term safety and efficacy for this vaccin/e will occur, but it cannot be in the context of maintaining a placebo group....establishment of a correlate of protection has not been feasible.'

Put simply, they have no idea how long the vaccine will prevent Covid-19, whether it just prevents symptoms and not infection and what constitutes 'protection'. They don't know if it's safe yet but as they aren't prepared to leave the placebo group unvaccinated so the long-term safety and efficacy data will come from the general public taking this trial vaccine.

Despite this, The NHS say 'The coronavirus (COVID-19) vaccine is safe and effective. It gives you the best protection against coronavirus', when they have no evidence that this is the case.

Prior Animal Studies and Their Implications for Human Trials

Scientists have been trying to develop coronavirus vaccines for decades but prior tests on animals meant they would be unsafe to extend to humans. When vaccines including those based on DNA were given to mice and ferrets, they developed antibodies but had auto-immune lung disease when challenged. Since the 1960's, it has been known that vaccinated animals can have antibody dependent enhancement of disease. That is, after being vaccinated they initially respond with high antibodies thought to correlate with immunity, but on being exposed to the wild virus, instead of being immune they develop a severe form of the illness. When cats were injected with a vaccine with the feline infectious peritonitis spike protein, using the same technology as the covid-19

mRNA vaccines, they died earlier than the unvaccinated animals when challenged with infectious peritonitis.

RSV is a similar respiratory virus to coronavirus. When a RSV vaccine was attempted in people without proper testing in 1965, the recipients produced antibodies and appeared well at first, but when they later came into contact with RSV, instead of being protected they contracted an enhanced version of the disease. Of the 20 babies who received the vaccine, 16 required hospitalisation, including two who died. Only one of the 21 babies who received the placebo was hospitalised (placebos are usually other vaccines) and no one died. Research into the vaccine was halted by the FDA in America.

Now specialists have warned that participants in covid-19 vaccine trials could not have given informed consent because they were not told that vaccines could worsen disease upon natural exposure. They wrote:

'The specific and significant COVID-19 risk of ADE should have been and should be prominently disclosed to research subjects currently in vaccine trials….in order to meet the medical ethics standard of patient comprehension for informed consent.'

Side-Effects

Side-effects experienced by trial participants included injection site pain, fever, fatigue, myalgia, arthralgia, lymphadenopathy, nausea, allergic reactions, injection site itching, pain in the extremities, osteoarthritis, psoriasis, insomnia and night sweats. There were four cases of Bell's palsy (facial paralysis).

There were two deaths in the vaccine group, which were dismissed as being unrelated to the vaccine because 'since other pre-existing diseases were more likely to have caused death than the vaccine'. This seems to be an assumption rather than anything grounded in science.

Since the experimental vaccine has been released on the public, further cases of shock and death have occurred. Dr. Moncef Slaoui of 'Operation Warp Speed', the programme to get the vaccine out as fast as possible, reported that rates of anaphylactic shock were 'superior to what one would expect with other vaccines'.

Two British and three Alaskan healthcare workers went into shock immediately after receiving the vaccine at the start of its rollout. Due to this, anyone having the vaccine is advised to wait in the doctor's surgery for 15 minutes after the jab. The UK's Yellow Card Reporting System now dispute the claims that the vaccine causes a high number of cases of shock, saying that it is rare and that the rate for the Pfizer jab is somewhere between 1 and 2 per 100,000 people. However, two healthcare workers who went into shock in the U.S were from the same hospital, a small regional hospital called Bartlett Regional Hospital in Juneau that employs a staff of 125 doctors. While V.A.N UK is unsure how many nurses are employed at the hospital, we are confident that the combined number of staff is far less than 100,000, yet two staff in the same facility had anaphylactic shock.

Norway is also investigating the vaccine in association with the deaths of 23 elderly frail people. The Norwegian Medicines Agency has so far looked at 13 of the deaths and concluded that the common adverse reactions of mRNA vaccines may have contributed to fatal outcomes in some of the frail patients.

Chinese health experts have called for all mRNA based vaccines to be suspended. An unnamed Chinese immunologist said

"The new mRNA vaccine was developed in haste and had never been used on a large scale for the prevention of infectious disease, and its safety had not been confirmed for large-scale use in humans."

The Paul Ehrlich Institute in Germany is also looking into the deaths of 10 people following the Pfizer/BioNtech vaccine. All those who died were between 79-93 years of age and had pre-existing conditions. The time between vaccination and death ranged from only a few hours to four days. All are said to have been gravely ill and receiving palliative care, which begs the question, why did they receive the vaccine in the first place? Giving a vaccine to someone who is already dying makes no sense, apart from the fact that severely ill individuals with unstable pre-existing conditions were never studied in any trial and the technology is entirely new.

In America, a doctor's death is being investigated following the covid-19 shot. 56 year old obstetrician Dr Gregory Michael developed an auto-immune blood disorder called acute immune thrombocytopenia (ITP) after being vaccinated. This occurs when the

immune system produces antibodies against platelets and prevents the blood from clotting.

Pfizer said in a statement that they did not believe their shot had anything to do with his death, but Dr Spivak, an Emeritus Professor of Medicine, said **"I think it is a medical certainty that the vaccine was related."**

He pointed out that if you vaccinate enough people, things like that will happen. This is why large scale trials should occur before a vaccine is released to the general public. Dr Spivak is convinced it was vaccine-related because the ITP developed very suddenly and severely after the shot - a pattern seen with other drugs. Another tell-tale aspect is that Dr Michael was younger than most patients who develop ITP for other reasons and he was a man. Most cases of ITP that are not medication related are in females who are over 70.

Dr Offit, inventor of the rotavirus vaccine and a spokesperson for the U.S vaccination programme, said that they'd 'keep their eyes open' to see if it happened to anyone else. He added **"Right now we're guessing".**

America's Vaccine Adverse Event Reporting System (VAERS), a voluntary reporting system that captures less than 1% of all vaccine reactions, has amassed reports of 181 people who died after being vaccinated with the covid-19 shot within the first two weeks of the vaccine programme being rolled out. The largest number of deaths occurred in the 75 plus age group, the age group that the vaccine was designed to protect.

As of February 2021, the UK's Yellow Card Reporting System has published its data on adverse events relating to covid-19 vaccines. They say that up to 31st January 2021 and after vaccinating over 8 million British people they had received 99 reports of Bell's Palsy (facial paralysis). They have also amassed 143 reports of death after the Pfizer vaccine and three reports where the vaccine brand was not specified.

Their data revealed further issues not highlighted in the trial participants, including 13 heart attacks (three of which were fatal), 12 cases deafness, two cases of sudden hearing loss, five cases of permanent blindness and a total of 823 eye disorders.

There were 269 cases of Covid-19 in Pfizer vaccinated British people, six cases that were asymptomatic (but positive on test) and 12 cases which were fatal. There were

seven vaccinated people who contracted pneumonia as a result of Covid-19 and two who died.

Covid-19 Vaccines and Prion Diseases

A paper in Microbiology and Infectious Diseases has highlighted that Covid-19 vaccines may have the potential to induce prion diseases like nvCJD. The researcher wanted to know if the spike protein used in the vaccine could convert TDP-43 and FUS to their prion based disease causing states. He pointed out that the vaccine had been introduced on an emergency basis without extensive testing and that serious adverse events to vaccination may not occur for 3-4 years after the vaccine is given so it is important to look more closely at possible effects. He wrote:

'Analysis of the Pfizer vaccine against COVID-19 identified two potential risk factors for inducing prion disease is humans. The RNA sequence in the vaccine contains sequences believed to induce TDP-43 and FUS to aggregate in their prion based conformation…'

Contraindications and Warnings

The only absolute contraindication to this vaccine is history of allergy to any of the vaccine ingredients or excipients.

The vaccine should not be given to anyone under the age of 16.

Any person undergoing anticoagulant therapy or those with a bleeding disorder should not have the vaccine.

Vaccination should be postponed in people with acute febrile illness.

Vaccination should be deferred in pregnancy. Pregnant women were excluded from the trials. 9 trial participants became pregnant during the trial and were withdrawn. They are being followed up to discover the outcome.

It is not known if the vaccine is excreted in human milk. The breastfeeding network say:

“There have been no lactating mothers in the study populations of either vaccine and the decision has been made based on an understanding of the way that vaccines are handled by a lactating mother’s body. However, further studies will be undertaken as soon as possible to confirm the information on low risk.”

Despite this, they say mothers can have the vaccine and continue to breastfeed. If mothers decide to do this, they will be partaking in a medical trial.

Effects on fertility have never been studied in humans. Initial animal studies indicate no reproductive toxicity.

The vaccine has never been studied when administered with other vaccines.

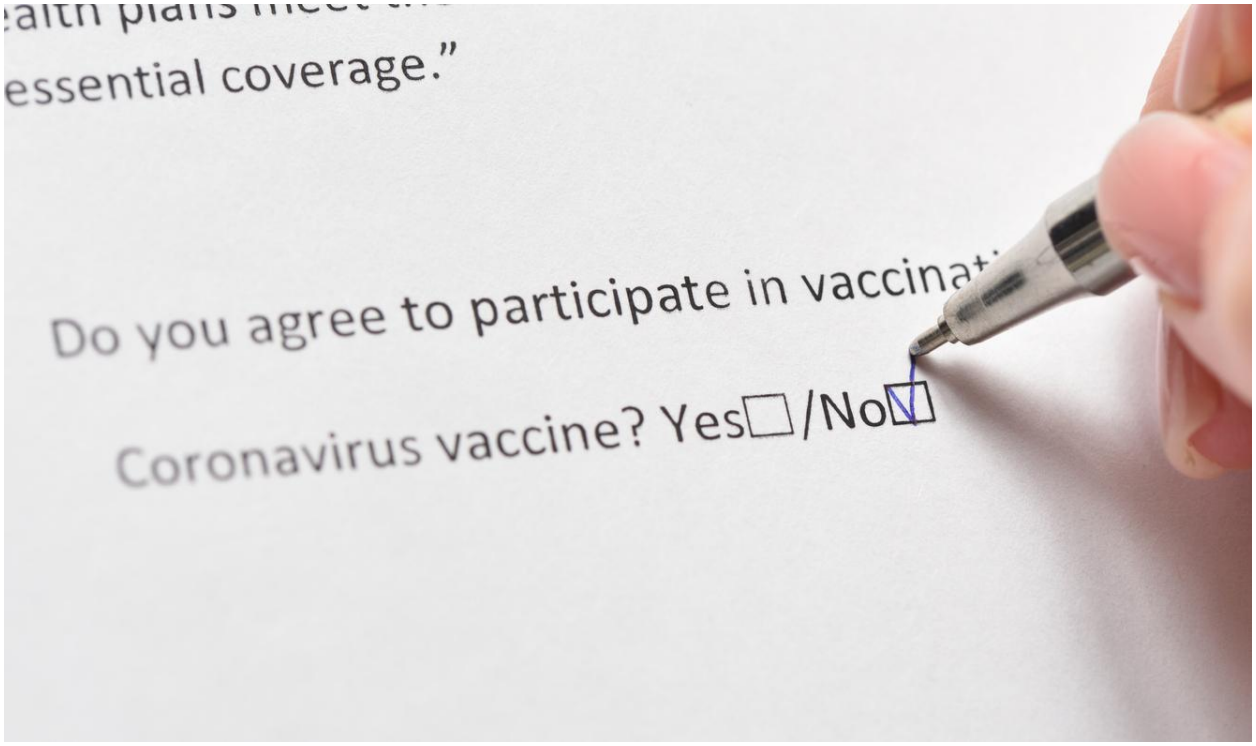
The adverse events associated with the vaccine may temporarily affect the ability to drive or operate machinery.

Is the Covid-19 Vaccine Mandatory?

The British Prime Minister, Boris Johnson, has said that like other vaccinations, the covid-19 vaccine will be entirely voluntary. On 2nd December 2020, he said, "There is no part of our culture or our ambition in this country to make vaccines mandatory." He did, however, say that he strongly urged people to take it.

It is also voluntary for healthcare workers and places of employment have no legal basis with which to force vaccination on their workers. They might do so as part of their private health and safety policy, although doing so would leave them open to discrimination and unfair dismissal claims if it is related to a protected characteristic under UK law. For example, if a worker refuses the vaccine on the basis of a health condition or pregnancy. Mandatory vaccination in the workplace could also infringe a worker's right to privacy under the Human Rights Act 1998, particularly when less invasive health and safety measures are available.

No medical procedure can be carried out without consent on a person who has the capacity to give consent and in respect of trial medications the voluntary consent of the subject is essential. If vaccines are coerced then the vaccine provider is acting illegally.



Report an Adverse Event

If you or a loved one have had this vaccine and experienced side-effects, you can report them via the UK's Yellow Card Reporting System at https://coronavirus-yellowcard.mhra.gov.uk/

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