MHRA issues new advice, concluding a possible link between COVID-19 Vaccine AstraZeneca and extremely rare, unlikely to occur blood clots

- The MHRA is not recommending age restrictions in COVID-19 Vaccine AstraZeneca vaccine use.
- The MHRA's scientific review of UK reports of extremely rare and unlikely to occur specific blood clots with lowered platelets has concluded that the evidence of a link with COVID-19 Vaccine AstraZeneca is stronger but more work is still needed.
- By 31 March 20.2 million doses of the COVID-19 Vaccine AstraZeneca had been given in the UK meaning the overall risk of these blood clots is approximately 4 people in a million who receive the vaccine.
- Anyone who did not have these side effects should come forward for their second dose when invited.
- The data suggest there is a slightly higher incidence reported in the younger adult age groups and the MHRA advises that this evolving evidence should be taken into account when considering the use of the vaccine.
- The MHRA is now issuing updated guidance for healthcare professionals on how to minimise risks, as well as further advice on symptoms for vaccine recipients to look out for 4 or more days after vaccination.
- Vaccines are the best way to protect people from COVID-19 and have already saved thousands of lives. Everyone should continue to get their vaccination when asked to do so unless specifically advised otherwise.

The Joint Committee on Vaccination and Immunisation (JCVI) have also published a statement following reports of an extremely rare adverse event after vaccination with the first dose of the AstraZeneca COVID-19 vaccine.

This includes information on the use of the vaccine in those under 30.

Updated information is being provided for people and healthcare professionals on the possible risk of extremely rare and unlikely to occur specific types of blood clots following vaccination with the COVID-19 Vaccine AstraZeneca, the Medicines and Healthcare products Regulatory Agency (MHRA) said today.

The MHRA has undertaken a thorough review into UK reports of a very rare and unlikely to occur specific type of blood clot in the brain, known as cerebral venous sinus thrombosis (CVST) occurring together with low levels of platelets (thrombocytopenia) following vaccination with the COVID-19 Vaccine AstraZeneca. It is also considering other blood clotting cases (thromboembolic events) alongside low platelet levels.

These reports have been analysed by the Government's independent advisory

body, the Commission on Human Medicines (CHM) and its COVID-19 Vaccines Benefit Risk Expert Working Group, which includes lay representatives and advice from leading haematologists.

Up to and including 31 March 2021, the MHRA had received 79 UK reports of blood clotting cases alongside low levels of platelets following the use of the COVID-19 Vaccine AstraZeneca:

- 44 of the 79 cases were of CVST with thrombocytopenia
- 35 of the 79 cases were of thrombosis in other major veins with thrombocytopenia
- 79 cases occurred in 51 women and 28 men, aged from 18 to 79 years. It should be noted that more women have been vaccinated with COVID-19 Vaccine AstraZeneca than men.
- Sadly, 19 people have died out of the 79 cases – 13 females and 6 males. 11 out of the 19 people who died were under the age of 50, 3 of whom were under 30. 14 of these 19 cases were of CVST with thrombocytopenia and 5 were of thrombosis with thrombocytopenia.
- All 79 cases occurred after a first dose of the vaccine.

This risk, based on reports up to and including 31 March, is slightly higher than the risk calculated from the reports published up to and including 24 March. However, likelihood of these blood clots occurring is still extremely rare.

As a precaution, administration of COVID-19 Vaccine AstraZeneca in people of any age who are at higher risk of blood clots because of their medical condition should be considered only if benefits from the protection from COVID-19 infection outweighs potential risks.

Anyone who experienced cerebral or other major blood clots occurring with low levels of platelets after their first vaccine dose of COVID-19 Vaccine AstraZeneca should not have their second dose. Anyone who did not have these side effects should come forward for their second dose when invited.

Pregnancy predisposes to thrombosis, therefore women should discuss with their healthcare professional whether the benefits of having the vaccine outweigh the risks for them.

The MHRA recently confirmed that the evidence to date does not suggest that the COVID-19 Vaccine AstraZeneca causes venous thromboembolism without a low platelet count.

It is important to note that this type of blood clot together with lowered platelets can rarely occur naturally in unvaccinated people as well as in people with COVID-19 disease.

While the MHRA continues to investigate these cases, as a precautionary measure, anyone who has symptoms four days or more after vaccination is advised to seek prompt medical advice, such as:

- a new onset of severe or persistent headache, blurred vision, confusion or seizures

- develop shortness of breath, chest pain, leg swelling or persistent abdominal pain,
- unusual skin bruising or pinpoint round spots beyond the injection site

Dr June Raine, MHRA Chief Executive, said:

> Over 37 million doses of vaccines against COVID-19 have now been administered in the UK, saving thousands of lives through the biggest vaccination programme that has ever taken place in the UK.
>
> No effective medicine or vaccine is without risk. We continually monitor safety during widespread use of any vaccine. This is to ensure vaccines are performing as expected, to identify any new side effects that may arise, and to ensure the benefits continue to outweigh the risks.
>
> The public's safety is always at the forefront of our minds and we take every report of a suspected side effect very seriously indeed. We thoroughly analyse each and every report as we receive it and although the number of reports of CVST and other thromboembolic events has increased over the last week, so has the overall number of vaccinations administered, therefore these blood clots remain extremely rare and unlikely to occur.
>
> We ask anyone who suspects they have experienced a side effect linked with their COVID-19 vaccine to report it to the Coronavirus Yellow Card website.
>
> It is still vitally important that people come forward for their vaccination when invited to do so.

Professor Sir Munir Pirmohamed, Chair of the Commission on Human Medicines, said:

> The independent Commission on Human Medicines (CHM) and its COVID-19 Expert Working Group, together with leading haematologists, has conducted a rigorous scientific analysis of all available evidence regarding reports of thromboembolic events occurring together with low platelets and COVID-19 Vaccine AstraZeneca and usage of the vaccine in different age groups.

We have a rich source of data – the best data there is – and the MHRA and CHM will continue to keep this under close observation. The public deserve nothing less.

Slides from press conference

Slides from 7 April 2021 press briefing – Communicating the potential benefits and harms of the Astra-Zeneca COVID-19 vaccine (PDF, 360KB, 5 pages)

Notes to editor

- Up to and including 31 March we have received 2 reports of blood clots (thromboembolism) reported with thrombocytopenia for the Pfizer/BioNTech vaccine. By this date, approximately 11 million first doses and 3.5 million second doses had been given.
- The Expert Haematology Panel has issued guidance on thrombosis and thrombocytopenia possibly occurring after vaccination with COVID-19 vaccines. This includes information on presentation and typical laboratory features, and treatment recommendations. The guidance also includes advice on recommended investigations for possible cases.
- The Medicines and Healthcare products Regulatory Agency is responsible for regulating all medicines and medical devices in the UK. All our work is underpinned by robust and fact-based judgements to ensure that the benefits justify any risks.
- The Medicines and Healthcare products Regulatory Agency ('the agency') has three centres. The MHRA, the National Institute for Biological Standards and Control (NIBSC) and the Clinical Practice Research Datalink (CPRD). The agency is an executive agency of the Department of Health and Social Care.
- The Commission on Human Medicines is the UK Government's independent advisory body. It advises ministers on the safety, efficacy and quality of medicinal products.
- The COVID-19 Vaccines Benefit Risk Expert Working Group of the Commission on Human Medicines is formed from 27 experts from outside of the MHRA, including virologists, epidemiologists, immunologists and toxicologists.
- The MHRA encourages anyone to report any suspicion or concern they have beyond the known, mild side effects on the Coronavirus Yellow Card site. Reporters do not need to be sure of a link between a vaccine and a suspected side effect but are still encouraged to report.
- For more information on COVID-19 vaccine adverse reactions, see the MHRA's weekly report
- For more information on COVID-19 Vaccine AstraZeneca, see the MHRA's regulatory approval decision page