FOI 23/262 – study of vaccinated and unvaccinated people

REQUEST
3 May 2023

In order to see if the vaccinations work you need to do a study comparing unvaccinated people and vaccinated people. This is the basis stud so please provide it!

I want a study using at least one of the vaccine brands such as Pfizer.

MHRA RESPONSE
22 May 2023

Dear

Thank you for your email.

All vaccines are tested through three phases of clinical trials to ensure they meet the required standard. Phase 1 trials are with a small group of people to make sure there are no safety concerns and determines the appropriate dosage for the best immune response. Phase 2 trials are conducted on a larger group of people to check the vaccine works consistently and that the immune response is sufficient. Phase 3 trials test the vaccines on thousands of people for scientists to assess if the vaccine is producing immunity that will prevent disease. Usually, these phases are run in sequence, but in an effort to find a safe and effective Covid-19 vaccine as quickly as possible, once safety has been ascertained through Phase 1, Phases 2 and 3 are being run in parallel. Extensive checks and balances are required at every stage of the development of a vaccine, and this is no different for a Covid-19 vaccine. No stages in the vaccine development processes were bypassed.

The temporary authorisations for use of the COVID-19 vaccines in the UK followed a rigorous scientific assessment of all the available evidence of quality, safety and effectiveness by the UK regulator, the Medicines and Healthcare products Regulatory Agency (MHRA). The MHRA expert scientists and clinicians reviewed data from the laboratory pre-clinical studies, clinical trials, manufacturing and quality controls, product sampling and testing of the final vaccine, and also considered the conditions for its safe supply and distribution. The decision was made with advice from the Commission on Human Medicines (CHM), the government's independent expert scientific advisory body. Regarding the MHRA approval of the Pfizer/BioNTech, Moderna and the Oxford/AstraZeneca COVID-19 vaccines, further information (including information for physicians and recipients of the vaccine, and Public Assessment Reports [PARs] for each vaccine) are available on the MHRA website. Links to these are provided below:

https://eur01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.gov.uk%2Fgovernment%2Fpublications%2Fregulatory-approval-of-pfizer-biontech-vaccine-for-covid-19&data=05%7C01%7CMHRACustomerServices%40mhra.gov.uk%7Cdd7cd5445db84dc0a19e08db3ff9e10d%7Ce527ea5c62584cd2a27f8bd237ec4c26%7C0%7C0%7C638174114677067909%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=%2BBo%2BLd1SedWlF6Akquniba4yqbyDGz9PvELyyA107BY%3D&reserved=0

https://eur01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.gov.uk%2Fgovernment%2Fpublications%2Fregulatory-approval-of-covid-19-vaccine-astrazeneca&data=05%7C01%7CMHRACustomerServices%40mhra.gov.uk%7Cdd7cd5445db84dc0a19e08db3ff9e10d%7Ce527ea5c62584cd2a27f8bd237ec4c26%7C0%7C0%7C638174114677067909%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=ZL2Ai%2BbBOyxqgVmQONn1QU%2BaI4EnATwX3cLo66Csnyw%3D&reserved=0

https://eur01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.gov.uk%2Fgovernment%2Fpublications%2Fregulatory-approval-of-covid-19-vaccine-moderna&data=05%7C01%7CMHRACustomerServices%40mhra.gov.uk%7Cdd7cd5445db84dc0a19e08db3ff9e10d%7Ce527ea5c62584cd2a27f8bd237ec4c26%7C0%7C0%7C638174114677067909%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=JdZBIJMncBStDKzTg9GLPQNC%2Fa9KJ9UCOg07jfVmgEY%3D&reserved=0

Please note that a marketing authorisation was granted for the Pfizer/BioNTech vaccine (Comirnaty) following a European Commission (EC) decision on 21 December 2020 (PLGB 53632/0002). Further information is available on the European Medicines Agency (EMA) website, a link to this is provided below:

https://eur01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.ema.europa.eu%2Fen%2Fmedicines%2Fhuman%2FEPAR%2Fcomirnaty&data=05%7C01%7CMHRACustomerServices%40mhra.gov.uk%7Cdd7cd5445db84dc0a19e08db3ff9e10d%7Ce527ea5c62584cd2a27f8bd237ec4c26%7C0%7C0%7C638174114677067909%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=IrEuZ9OmjEa%2F3WCsh9xFimnzFIPI%2F0xSnNyp5ChoQEU%3D&reserved=0

Please also note that a marketing authorisation was granted for the Moderna vaccine on 31 March 2021 following an EC Reliance Procedure (PLGB 53720/0002). Further information is available on the MHRA website and the EMA website, links to these are provided below:

https://eur01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.gov.uk%2Fgovernment%2Fpublications%2Fregulatory-approval-of-covid-19-vaccine-moderna&data=05%7C01%7CMHRACustomerServices%40mhra.gov.uk%7Cdd7cd5445db84dc0a19e08db3ff9e10d%7Ce527ea5c62584cd2a27f8bd237ec4c26%7C0%7C0%7C638174114677067909%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=JdZBIJMncBStDKzTg9GLPQNC%2Fa9KJ9UCOg07jfVmgEY%3D&reserved=0

https://eur01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.ema.europa.eu%2Fen%2Fmedicines%2Fhuman%2FEPAR%2Fcovid-19-vaccine-moderna&data=05%7C01%7CMHRACustomerServices%40mhra.gov.uk%7Cdd7cd5445db84dc0a19e08db3ff9e10d%7Ce527ea5c62584cd2a27f8bd237ec4c26%7C0%7C0%7C638174114677067909%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=acFv8sdDQk0z5aPdV7tq8xjMMVNpvTes4Z%2F3oUkmpFk%3D&reserved=0

A marketing authorisation has been granted for the Janssen Covid-19 vaccine on 28 May 2021. Further information is available via the below link:

https://eur01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.gov.uk%2Fgovernment%2Fpublications%2Fregulatory-approval-of-covid-19-vaccine-janssen&data=05%7C01%7CMHRACustomerServices%40mhra.gov.uk%7Cdd7cd5445db84dc0a19e08db3ff9e10d%7Ce527ea5c62584cd2a27f8bd237ec4c26%7C0%7C0%7C638174114677067909%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=8aNaPqrWtmWHwCCDOl2kmXShJrGoSbr98ISQS%2FMf9Po%3D&reserved=0

In addition, a marketing authorisation was granted for the Oxford/AstraZeneca vaccine on 24 June 2021 following an EC Reliance Procedure (PLGB 17901/0355). Further information is available on the MHRA website and the EMA website, links to these are provided below:

https://eur01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.gov.uk%2Fgovernment%2Fpublications%2Fregulatory-approval-of-covid-19-vaccine-astrazeneca&data=05%7C01%7CMHRACustomerServices%40mhra.gov.uk%7Cdd7cd5445db84dc0a19e08db3ff9e10d%7Ce527ea5c62584cd2a27f8bd237ec4c26%7C0%7C0%7C638174114677067909%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=ZL2Ai%2BbBOyxqgVmQONn1QU%2BaI4EnATwX3cLo66Csnyw%3D&reserved=0

https://eur01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.ema.europa.eu%2Fen%2Fmedicines%2Fhuman%2FEPAR%2Fvaxzevria-previously-covid-

19-vaccine-astrazeneca&data=05%7C01%7CMHRACustomerServices%40mhra.gov.uk%7Cdd7cd5445db84dc0a19e08db3ff9e10d%7Ce527ea5c62584cd2a27f8bd237ec4c26%7C0%7C0%7C638174114677067909%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=9%2FeH9jBIbVetRJYa9GT5VjQhAyqFyzGwsMiAySSiHfI%3D&reserved=0

A marketing authorisation was granted for Valneva suspension for injection (PL 43185/0002) on 13 April 2022. A link to the Public Assessment Report is provided below:

https://eur01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fmhraproducts4853.blob.core.windows.net%2Fdocs%2F27680d2f701880f90f62740cab6adb4d939b54b4&data=05%7C01%7CMHRACustomerServices%40mhra.gov.uk%7Cdd7cd5445db84dc0a19e08db3ff9e10d%7Ce527ea5c62584cd2a27f8bd237ec4c26%7C0%7C0%7C638174114677067909%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=tkdmDAasfEwEN9S0sOwCHqF16x%2FRlQEO8f1HEz5GJo4%3D&reserved=0

Further information on other vaccines for Covid-19, including the bivalent vaccines are available on the MHRA website, please see the link below:

https://eur01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fmhraproducts4853.blob.core.windows.net%2Fdocs%2F27680d2f701880f90f62740cab6adb4d939b54b4&data=05%7C01%7CMHRACustomerServices%40mhra.gov.uk%7Cdd7cd5445db84dc0a19e08db3ff9e10d%7Ce527ea5c62584cd2a27f8bd237ec4c26%7C0%7C0%7C638174114677224120%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=CLJ34xZTgDabk6fQJ6GOFtIHxU5icsN1VvI3mFyqSDs%3D&reserved=0

MHRA has authorised the Spikevax and Comirnaty bivalent vaccines for use in protecting against Covid-19 infection. Links to further information, including the Public Assessment Reports (PARs) published by the European Medicines Agency and MHRA are provided below:

https://eur01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fproducts.mhra.gov.uk%2Fsearch%2F%3Fsearch%3DSpikevax%26page%3D1&data=05%7C01%7CMHRACustomerServices%40mhra.gov.uk%7Cdd7cd5445db84dc0a19e08db3ff9e10d%7Ce527ea5c62584cd2a27f8bd237ec4c26%7C0%7C0%7C638174114677224120%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=iqtEkj1j%2FTSo1HsojIMQxyuGfUEhKFQlLLc76r%2Fa6FA%3D&reserved=0

https://eur01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fproducts.mhra.gov.uk%2Fsearch%2F%3Fsearch%3DComirnaty%26page%3D1&data=05%7C01%7CMHRACustomerServices%40mhra.gov.uk%7Cdd7cd5445db84dc0a19e08db3ff9e10d%7Ce527ea5c62584cd2a27f8bd237ec4c26%7C0%7C0%7C638174114677224120%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=KhZju6Q11pDwU26DnZVHcADSeaJZ70y5Hwsxy%2BD9j5A%3D&reserved=0

https://eur01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.ema.europa.eu%2Fen%2Fmedicines%2Fhuman%2FEPAR%2Fcomirnaty&data=05%7C01%7CMHRACustomerServices%40mhra.gov.uk%7Cdd7cd5445db84dc0a19e08db3ff9e10d%7Ce527ea5c62584cd2a27f8bd237ec4c26%7C0%7C0%7C638174114677224120%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=hpEKwoK3Hsli5NqyFX89zQUdOjEPvhbDJGogNy1Dtto%3D&reserved=0

https://eur01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.ema.europa.eu%2Fen%2Fmedicines%2Fhuman%2FEPAR%2Fspikevax&data=05%7C01%7CMHRACustomerServices%40mhra.gov.uk%7Cdd7cd5445db84dc0a19e08db3ff9e10d%7Ce527ea5c62584cd2a27f8bd237ec4c26%7C0%7C0%7C638174114677224120%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=wKuRFcY9bonxcnN8zgSL2PSPb0ToEPQwErfF2yfiPTY%3D&reserved=0

If you are dissatisfied with the handling of your request, you have the right to ask for an internal review. Internal review requests should be submitted within two months of the date you receive this response and addressed to: info@mhra.gov.uk

If you remain dissatisfied following any internal review, you may ask the Information Commissioner (ICO) to decide on whether or not we have interpreted the FOIA correctly in dealing with the request and subsequent internal review. Please bear in mind that the Information Commissioner will not normally review our handling of your request unless you have first contacted us to conduct an internal review. The ICO's address is:

The Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF

Yours sincerely

MHRA Customer Experience Centre

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