

Risk of myocarditis and pericarditis following COVID-19 vaccination in England and Wales

Sample size

Dose 1

exposure	England	Wales	total
BNT162b2	8623532	798948	9422480
ChAdOx1-S	15945751	1206764	17152515
Comparator	25630910	610141	26241051
Total	50200193	2615853	52816046

Dose 2

exposure	England	Wales	total
BNT162b2	8242459	680811	8923270
ChAdOx1-S	8052178	1163684	9215862
Comparator	8276329	195006	8471335
Total	24570966	2039501	26610467

Estimates, overall

Dose 1

nation	exposure	days_post_vaccination	estimate	conf.low	conf.high	p.value
All	BNT162b2	0-13	0.57	0.39	0.83	0.00
All	BNT162b2	14+	0.80	0.66	0.97	0.03
All	ChAdOx1-S	0-13	0.66	0.50	0.88	0.00
All	ChAdOx1-S	14+	0.77	0.65	0.91	0.00
England	BNT162b2	0-13	0.58	0.39	0.84	0.00
England	BNT162b2	14+	0.80	0.65	0.97	0.03
England	ChAdOx1-S	0-13	0.67	0.50	0.89	0.01
England	ChAdOx1-S	14+	0.75	0.63	0.90	0.00
Wales	BNT162b2	0-13	0.41	0.06	2.89	0.37
Wales	BNT162b2	14+	0.92	0.26	3.20	0.89
Wales	ChAdOx1-S	0-13	0.53	0.12	2.30	0.39
Wales	ChAdOx1-S	14+	1.15	0.53	2.48	0.72

Dose 2

nation	exposure	days_post_vaccination	estimate	conf.low	conf.high	p.value
All	BNT162b2	0-13	1.12	0.77	1.63	0.56
All	BNT162b2	14+	1.47	1.14	1.91	0.00
All	ChAdOx1-S	0-13	1.20	0.78	1.85	0.40
All	ChAdOx1-S	14+	1.29	0.82	2.04	0.26
England	BNT162b2	0-13	0.96	0.65	1.43	0.84
England	BNT162b2	14+	1.44	1.10	1.89	0.01
England	ChAdOx1-S	0-13	1.21	0.78	1.87	0.40
England	ChAdOx1-S	14+	1.28	0.80	2.03	0.31
Wales	BNT162b2	0-13	4.63	1.39	15.43	0.01
Wales	BNT162b2	14+	1.95	0.71	5.35	0.19
Wales	ChAdOx1-S	0-13	1.14	0.11	11.34	0.91
Wales	ChAdOx1-S	14+	1.65	0.24	11.26	0.61

Estimates, by sex

Reported for England only due to insufficient events in the subgroups in Wales.

Dose 1

exposure	days_post_vaccination	sex	estimate	conf.low	conf.high	p.value
BNT162b2	0-13	Male	0.38	0.21	0.70	0.01
BNT162b2	0-13	Female	0.84	0.52	1.35	0.92
BNT162b2	14+	Male	0.81	0.63	1.03	0.30
BNT162b2	14+	Female	0.78	0.60	1.03	0.29
ChAdOx1-S	0-13	Male	0.79	0.56	1.10	0.49
ChAdOx1-S	0-13	Female	0.48	0.29	0.81	0.02
ChAdOx1-S	14+	Male	0.83	0.68	1.02	0.25
ChAdOx1-S	14+	Female	0.63	0.48	0.82	0.00

Dose 2

exposure	days_post_vaccination	sex	estimate	conf.low	conf.high	p.value
BNT162b2	0-13	Male	0.86	0.50	1.49	0.97
BNT162b2	0-13	Female	1.10	0.63	1.93	1.00
BNT162b2	14+	Male	1.40	0.98	1.99	0.23
BNT162b2	14+	Female	1.50	1.02	2.20	0.14
ChAdOx1-S	0-13	Male	1.13	0.65	1.97	0.99
ChAdOx1-S	0-13	Female	1.33	0.70	2.50	0.85
ChAdOx1-S	14+	Male	0.98	0.51	1.87	1.00
ChAdOx1-S	14+	Female	1.71	0.92	3.17	0.31

Estimates, by age group

Reported for England only due to insufficient events in the subgroups in Wales.

Dose 1

exposure	days_post_vaccination	age_group	estimate	conf.low	conf.high	p.value
BNT162b2	0-13	<40	1.56	0.64	3.78	0.90
BNT162b2	0-13	40-69	0.81	0.48	1.39	0.97
BNT162b2	0-13	70+	0.29	0.15	0.55	0.00
BNT162b2	14+	<40	1.44	0.89	2.32	0.58
BNT162b2	14+	40-69	1.13	0.88	1.45	0.91
BNT162b2	14+	70+	0.47	0.36	0.63	0.00
ChAdOx1-S	0-13	<40	1.64	0.85	3.18	0.60
ChAdOx1-S	0-13	40-69	0.73	0.51	1.05	0.42
ChAdOx1-S	0-13	70+	0.33	0.18	0.60	0.00
ChAdOx1-S	14+	<40	1.42	0.94	2.15	0.47
ChAdOx1-S	14+	40-69	0.92	0.74	1.13	0.96
ChAdOx1-S	14+	70+	0.43	0.32	0.57	0.00

Dose 2

exposure	days_post_vaccination	age_group	estimate	conf.low	conf.high	p.value
BNT162b2	0-13	<40	1.76	0.76	4.08	0.71
BNT162b2	0-13	40-69	0.52	0.21	1.26	0.61
BNT162b2	0-13	70+	1.09	0.64	1.86	1.00
BNT162b2	14+	<40	1.52	0.75	3.08	0.81
BNT162b2	14+	40-69	1.15	0.68	1.95	1.00
BNT162b2	14+	70+	1.59	1.13	2.25	0.05
ChAdOx1-S	0-13	<40	1.11	0.27	4.60	1.00
ChAdOx1-S	0-13	40-69	1.85	1.08	3.15	0.14
ChAdOx1-S	0-13	70+	0.71	0.34	1.50	0.94
ChAdOx1-S	14+	<40	0.72	0.10	5.17	1.00
ChAdOx1-S	14+	40-69	1.13	0.49	2.59	1.00
ChAdOx1-S	14+	70+	1.43	0.81	2.53	0.77

Heterogeneity p-values

Reported for England only due to insufficient events in the subgroups in Wales.

Dose 1

Sex

exposure	days_post_vaccination	p.value
BNT162b2	0-13	0.04
BNT162b2	14+	0.87
ChAdOx1-S	0-13	0.11
ChAdOx1-S	14+	0.08

Age group

exposure	days_post_vaccination	p.value
BNT162b2	0-13	0
BNT162b2	14+	0
ChAdOx1-S	0-13	0
ChAdOx1-S	14+	0

Dose 2

Sex

exposure	days_post_vaccination	p.value
BNT162b2	0-13	0.53
BNT162b2	14+	0.78
ChAdOx1-S	0-13	0.69
ChAdOx1-S	14+	0.21

Age group

exposure	days_post_vaccination	p.value
BNT162b2	0-13	0.14
BNT162b2	14+	0.61
ChAdOx1-S	0-13	0.10
ChAdOx1-S	14+	0.81

Estimated excess risk 90 days post vaccination

Reported for England only.

exposure	dose1	dose2
BNT162b2	-50	43
ChAdOx1	-102	30

Contributions to this work

This work was conducted on behalf of the BHF Data Science Centre (Health Data Research UK) CVD-COVID-UK/COVID-IMPACT Consortium and the Longitudinal Health and Wellbeing and Data and Connectivity UK COVID-19 National Core Studies. Samantha Ip developed the analysis code and implemented the analysis in England; Fatemeh Torabi derived the dataset for Wales and implemented the analysis in Wales; and Venexia Walker derived the dataset for England, combined and visualised the results from both nations, and drafted the report. The work relied on the support of the CCU002 project group, members of which include: Angela Wood (University of Cambridge), Arun Karthikeyan Suseeladevi (University of Bristol), Ashley Akbari (Swansea University), Cathie Sudlow (BHF Data Science Centre), Emanuele Di Angelantonio (University of Cambridge), Efosa Omigie (NHS Digital), Fatemeh Torabi (Swansea University), Hoda Abbasizanjani (Swansea University), Jennifer Cooper (University of Bristol), Jonathan Sterne (University of Bristol), Rachel Denholm (University of Bristol), Rochelle Knight (University of Bristol), Sam Hollings (NHS Digital), Samantha Ip (University of Cambridge), Spencer Keene (University of Cambridge), Spiros Denaxas (University College London), Teri-Louise North (University of Bristol), Thomas Bolton (BHF Data Science Centre), Venexia Walker (University of Bristol) and William Whiteley (University of Edinburgh). The project was conceived by this group, all members of which contributed to the development of the protocol (https://github.com/BHFDSC/CCU002_03/blob/main/protocol/COVID%20vaccination%20and%20myocarditis%20and%20pericarditis.pdf). Members of the group also reviewed and discussed analysis results and their interpretation, including in the context of other relevant published studies.

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Other acknowledgements

This work makes use of de-identified data held in NHS Digital's TRE for England and the SAIL Databank for Wales, made available via the BHF Data Science Centre's CVD-COVID-UK/COVID-IMPACT consortium. This work uses data provided by patients and collected by the NHS as part of their care and support. We would like to acknowledge all data providers who make health relevant data available for research.

This study makes use of anonymised data held in the Secure Anonymised Information Linkage (SAIL) Databank. This work uses data provided by patients and collected by the NHS as part of their care and support. We would also like to acknowledge all data providers who make anonymised data available for research. We wish to acknowledge the collaborative partnership that enabled acquisition and access to the de-identified data, which led to this output. The collaboration was led by the Swansea University Health Data Research UK team under the direction of the Welsh Government Technical Advisory Cell (TAC) and includes the following groups and organisations: the SAIL Databank, Administrative Data Research (ADR) Wales, Digital Health and Care Wales (DHCW), Public Health Wales, NHS Shared Services Partnership (NWSSP) and the Welsh Ambulance Service Trust (WAST). All research conducted has been completed under the permission and approval of the SAIL independent Information Governance Review Panel (IGRP) project number 0911.

Data availability

The data used in this study are available in NHS Digital's TRE for England, but as restrictions apply they are not publicly available (<https://digital.nhs.uk/coronavirus/coronavirus-data-services-updates/trusted-research-environment-service-for-england>). The CVD-COVID-UK/COVID-IMPACT programme led by the BHF Data Science Centre (<https://www.hdruc.ac.uk/helping-with-health-data/bhf-data-science-centre/>) received approval to access data in NHS Digital's TRE for England from the Independent Group Advising on the Release of Data (IGARD) (<https://digital.nhs.uk/about-nhs-digital/corporate-information-and-documents/independent-group-advising-on-the-release-of-data>) via an application made in the Data Access Request Service (DARS) Online system (ref. DARS-NIC-381078-Y9C5K) (<https://digital.nhs.uk/service-s/data-access-request-service-dars/dars-products-and-services>). The CVD-COVID-UK/COVID-IMPACT Approvals & Oversight Board (<https://www.hdruc.ac.uk/projects/cvd-covid-uk-project/>) subsequently granted approval to this project to access the data within the TRE for England and the Secure Anonymised Information Linkage (SAIL) Databank. The de-identified data used in this study was made available to accredited researchers only.

The data used in this study are available in the SAIL Databank at Swansea University, Swansea, UK, but as restrictions apply they are not publicly available. All proposals to use SAIL data are subject to review by an independent Information Governance Review Panel (IGRP). Before any data can be accessed, approval must be given by the IGRP. The IGRP gives careful consideration to each project to ensure proper and appropriate use of SAIL data. When access has been granted, it is gained through a privacy protecting safe haven and remote access system referred to as the SAIL Gateway. SAIL has established an application process to be followed by anyone who would like to access data via SAIL at <https://www.saildatabank.com/application-process>

Ethical approval

The North East-Newcastle and North Tyneside 2 research ethics committee provided ethical approval for the CVD-COVID-UK/COVID-IMPACT research programme (REC No 20/NE/0161).