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Combining recombinant herpes zoster and influenza or COVID-19 vaccination

Submission date
16/11/2022

Recruitment status
No longer recruiting

Registration date
30/05/2023

Overall study status
Completed

Last Edited
18/11/2026

Condition category
Infections and Infestations

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Shingles is a common and painful disease, it can result in long-term pain and in rare cases can even be fatal. It is recommended that all adults in the UK are offered the shingles vaccine on their 70th birthday. Uptake of the shingles vaccine is suboptimal, therefore strategies to improve uptake are needed.
Routine reporting of the shingles vaccine suggests that uptake is greater during the influenza season, and it is assumed this is due to it being offered at the same time as the annual flu vaccine. A new vaccine for shingles has been recommended since 2021, a recombinant herpes zoster vaccination.
Up until May 2023 concomitant administration of RZV with either adjuvanted or COVID-19 vaccine (C19) was not recommended due to concern about misattribution of side-effects and limited experience with COVID-19 vaccines. The policy was updated in May 2023 to allow co-administration of COVID-19 vaccines with any vaccine. This was based on recent evidence supporting the acceptable safety profile of a COVID-19 vaccine with RZV and to improve timely protection and uptake. There is still a need however for safety data with co-administration of second dose of RZV as the adverse event profile differs between the doses and there is a lack of published data on the safety and immunogenicity of RZV and adjuvanted flu vaccine.

Who can participate?
Healthy volunteers aged 50 years and over who have not received a live shingles vaccine within 5 years

What does the study involve?
Participants will be required to attend six study appointments over a period of 5 months at their nearest participating site. They will be randomly allocated into one of five groups, and they do not know which group they are in. Participants will be required to provide blood samples at study visits, and complete an e-diary in-between visits.

What are the possible benefits and risks of participating?
The potential benefits will be protection against COVID-19, Herpes zoster and influenza. However, some participants may already be up to date with their COVID-19 and flu vaccines, and the additional COVID-19 and flu vaccine as part of the study would not offer them additional

protection.
Localised bruising and discomfort can occur at the site of blood sampling. Infrequently fainting may occur. The total volume of blood drawn over a 6-week period will be approximately 260 ml (blood volumes may vary slightly for participants at different investigator sites due to the use of different volume vacutainers, following local Trust procedures). This should not compromise these otherwise healthy volunteers, as these volumes are within the limits of 470 ml every 3–4 months for blood donations to the National Blood Transfusion Service.
Allergic reactions from mild to severe may occur in response to any constituent of a medicinal product's preparation. Anaphylaxis is extremely rare (about 1 in 1,000,000 vaccine doses) but can occur in response to any vaccine or medication. People very often have tenderness, pain, warmth, redness, itching, swelling or bruising or less commonly have a small lump in their arm where they have been vaccinated. After vaccination it is common to experience the following side effects for all vaccines: fatigue, joint aches, muscle aches, headaches, feeling sick/nauseated /vomiting or diarrhea, flu-like symptoms, such as high temperature, sore throat, runny nose, cough and chills, feeling unwell. With the shingles vaccine 1 in 10 people may experience these common side effects that are severe enough to interfere with their daily activities. They usually last for less than a week (more commonly 24-48 hours after vaccination). Other less common side effects are: abdominal pain, feeling dizzy, excessive sweating, itching skin or rash, decreased appetite, and swollen lymph nodes.

Where is the study run from?
University of Bristol (UK)

When is the study starting and how long is it expected to run for?
November 2022 to November 2025

Who is funding the study?
GlaxoSmithKline (UK)

Who is the main contact?
Ms Rachael Heys, zosterflucov-trial@bristol.ac.uk

Contact information

Type(s)
Scientific, Public

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Ms Rachael Heys

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Type(s)

Principal investigator

Contact name
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Additional identifiers

Integrated Research Application System (IRAS)
1006696

Central Portfolio Management System (CPMS)
54747

Protocol serial number
VT/2022/7349

Study information

Scientific Title
A phase IV, multi-centre, randomised controlled trial to assess immunogenicity and safety of COVID-19 and seasonal influenza vaccine given to healthy adults or those with underlying medical conditions when co-administered with a recombinant herpes zoster vaccine with adjuvant

Acronym
ZosterFluCOV

Study objectives
The ZosterFluCov study aims to evaluate whether shingles (herpes zoster) vaccine can be co-administered with an mRNA COVID-19 (Bivalent) vaccine or an adjuvanted influenza vaccine (aQIV) without a significant immune interference or adverse reactions of the COVID-19, influenza or RZ vaccines.

1. Cell-mediated responses to two doses of RZV, 1 month after the 2nd dose, given alone compared to co-administration with Bivalent vaccine with 1st or 2nd dose of RZV.
2. Exploratory evaluation of CD4+T-cells against COVID-19 after vaccination with RZV or aQIV in the CMI cohort.
3. S and N- protein immunoglobulin, before and 1 month after first vaccination in the exploratory immunology cohort.
4. Solicited systemic AEs over 7 days after 1st and 2nd doses of RZV given alone compared to co-administration with either Bivalent vaccine or aQIV.
5. Solicited local adverse reactions over 7 days after 1st and 2nd doses of RZV given alone

compared to co-administration with either Bivalent vaccine or aQIV.
6. Grade 3 and 4 SSR after 1st RZV dose in group 1, 2 and 5 compared to grade 3 SSR after 1st dose of RZV with Bivalent vaccine in group 3
7. Grade 3 and 4 SSR after 2nd dose of RZV in group 1, 3 and 4 compared to grade 3 SSR after 2nd dose RZV
8. Describe participant and study nurse attitudes to vaccine co-administration. (added 23/11 /2023)

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 26/05/2023, South Central - Hampshire B Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 207 1048 088; hampshireb.rec@hra.nhs.uk), ref: 22/SC/0409

Primary study design
Interventional

Study design
Double-blind randomized controlled parallel-group trial

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Shingles, influenza, COVID-19 (SARS-CoV-2 infection)

Interventions
Current interventions as of 22/10/2024:
To test the immunogenicity and safety of giving the recombinant herpes zoster with adjuvant (shingles) vaccine, at the same time as either the COVID-19 bivalent mRNA vaccine or the flu vaccine.

Participants will be randomised by a computer in a 1:1:2:2:2 ratio to one of five groups; 129 participants to groups 1 and 2, and 258 participants to groups 3-5. Only 129 participants in group 3 will progress to the second and third vaccination time points required to assess COVID-19 vaccine/RZV co-administration. All five groups will receive two doses of RZV (except participants in group 3 who do not progress after the first vaccination timepoint and will not have any RZV doses as part of the trial). At the first and second vaccination timepoints, participants will receive two injections (combinations of RZV, COVID-19 vaccine, aQIV or placebo [P]). At the final vaccination visit participants will receive one injection (either a second RZV or flu or COVID-19 vaccine).

Vaccines administered at visit 1, visit 3, and visit 5, respectively:
Group 1: COVID-19/P, RZV/P, RZV
Group 2: RZV/P, RZV/COVID-19, Flu
Group 3: aQIV/P, COVID-19/RZV, RZV
Group 4: RZV/aQIV, RZV/P, COVID-19
Group 5: RZV/P, RZV/aQIV, COVID-19

Group 1 will receive aQIV at visit 6 (day 140)

Each participant will be in the study for 5 months and attend 6 study visits.

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Previous interventions as of 09/01/2024 to 22/10/2024:
To test the immunogenicity and safety of giving the recombinant herpes zoster with adjuvant (shingles) vaccine, at the same time as either the COVID-19 bivalent mRNA vaccine or the flu vaccine.

Participants will be randomised by a computer in a 1:1:2:2:2 ratio to one of five groups; 129 participants to groups 1 and 2, and 258 participants to groups 3-5. Only 129 participants in group 3 will progress to the second and third vaccination time points required to assess Bivalent vaccine/RZV co-administration. All five groups will receive two doses of RZV (except participants in group 3 who do not progress after the first vaccination timepoint and will not have any RZV doses as part of the trial). At the first and second vaccination timepoints, participants will receive two injections (combinations of RZV, COVID-19 vaccine, aQIV or placebo [P]). At the final vaccination visit participants will receive one injection (either a second RZV or flu or COVID-19 vaccine).

Vaccines administered at visit 1, visit 3, and visit 5, respectively:
Group 1: COVID-19/P, RZV/P, RZV
Group 2: RZV/P, RZV/COVID-19, Flu
Group 3: aQIV/P, COVID-19/RZV, RZV
Group 4: RZV/aQIV, RZV/P, COVID-19
Group 5: RZV/P, RZV/aQIV, COVID-19

Group 1 will receive aQIV at visit 6 (day 140)

Each participant will be in the study for 5 months and attend 6 study visits.

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Previous interventions:
To test the immunogenicity and safety of giving the recombinant herpes zoster with adjuvant (shingles) vaccine, at the same time as either the COVID-19 bivalent mRNA vaccine or the flu vaccine.

Participants will be randomised by a computer in a 1:1:2:2:2 ratio to one of five groups; 129 participants to groups 1 and 2, and 258 participants to groups 3-5. Only 129 participants in group 3 will progress to the second and third vaccination time points required to assess Bivalent vaccine/RZV co-administration. A subset of sites will be selected that will administer the second and third vaccination timepoints. All five groups will receive two doses of RZV (except participants in group 3 who do not progress after the first vaccination timepoint and will not have any RZV doses as part of the trial). At the first and second vaccination timepoints, participants will receive two injections (combinations of RZV, Bivalent vaccine, aQIV or placebo [P]). At the final vaccination visit participants will receive one injection (either a second RZV or placebo).

Vaccines administered at D0, D56, and D112, respectively:
Group 1: Bivalent/P, RZV/P, RZV
Group 2: RSV/P, RZV/bivalent, P

Group 3: aQIV/P, Bivalent/RZV, RZV
Group 4: RZV/aQIV, RZV/P, P
Group 5: RZV/P, RZV/aQIV, P

Each participant will be in the study for 5 months and attend 6 study visits.

Intervention Type
Biological/Vaccine

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Comirnaty JN.1(30 micrograms)/ dose dispersion for injection COVID-19 mRNA Vaccine (nucleoside modified), adjuvanted quadrivalent influenza vaccine [influenza virus surface antigens (haemagglutinin and neuraminidase), inactivated], herpes zoster vaccine (recombinant adjuvanted) [Varicella Zoster Virus 1 glycoprotein E antigen]

Primary outcome(s)
Current primary outcome measure as of 22/10/2024:
Immunogenicity:
1. Immunogenicity, measured by S-binding total Ig, 1 month after COVID-19 vaccine given alone compared to coadministration with RZV (first or second dose)
2. Immunogenicity, measured by haemagglutination inhibition assay (HAI), 1 month after aQIV for all four strains included in the vaccine given alone compared to coadministration with RZV
3. Immunogenicity of two doses of RZV vaccine, measured by total antibody against glycoprotein E (total anti-gE antibody concentrations) measured by enzyme-linked immunosorbent assay (ELISA), 1 month after the second dose, given alone, compared to coadministration with COVID-19 vaccine or aQIV with either the first or second dose of RZV

Safety:
1. Rate of grade 3 and 4 solicited systemic adverse reactions (SSR) recorded over 7 days after 1st and 2nd doses of RZV given alone compared to coadministration with COVID-19 vaccine
2. Rate of grade 3 and 4, solicited systemic adverse reactions recorded over 7 days after 1st and 2nd doses of RZV given alone compared to co-administration with aQIV

Previous primary outcome measure:
Immunogenicity:
1. Immunogenicity, measured by S-binding total Ig, 1 month after Bivalent vaccine given alone compared to coadministration with RZV (first or second dose)
2. Immunogenicity, measured by haemagglutination inhibition assay (HAI), 1 month after aQIV for all four strains included in the vaccine given alone compared to coadministration with RZV
3. Immunogenicity of two doses of RZV vaccine, measured by total antibody against glycoprotein E (total anti-gE antibody concentrations) measured by enzyme-linked immunosorbent assay (ELISA), 1 month after the second dose, given alone, compared to coadministration with Bivalent vaccine or aQIV with either the first or second dose of RZV

Safety:
1. Rate of grade 3 and 4 solicited systemic adverse reactions (SSR) recorded over 7 days after 1st

and 2nd doses of RZV given alone compared to coadministration with Bivalent vaccine
2. Rate of grade 3 and 4, solicited systemic adverse reactions recorded over 7 days after 1st and 2nd doses of RZV given alone compared to co-administration with aQIV

Key secondary outcome(s)

Current secondary outcome measure as of 22/10/2024:
1. Cell-mediated responses to two doses of RZV, measured using glycoprotein E specific CD4+ cells measured by intracellular cytokine staining 1 month after the second dose, given alone compared to co-administration with COVID-19 vaccine with 1st or 2nd dose of RZVA
2. Exploratory evaluation of CD4+ T-cells against COVID-19 using S and N protein-specific T-cells measured by ELISpot after vaccination with RZVor aQIV (CMI cohort)
3. N- N-protein immunoglobulin measured using total antibody against N-protein (total anti-N protein antibody concentration) measured by electrochemiluminescence immunoassay (ECLIA) before and 1 month after the first vaccination in the (exploratory immunology cohort
4. Grade 3 and 4 SSR recorded after 1st RZV dose in group 1 (day 56), group 2 and 5 (day 0) compared to grade 3 SSR recorded after 1st dose of RZV with COVID-19 vaccine in group 3 (day 56)
5. Grade 3 and 4 SSR recorded after 1st dose RZV in group 1 (day 56), group 2 and 5 (day 0) compared to grade 3 SSR recorded after 1st dose of RZV with aQIV in group 4 (day 0)
6. Grade 3 and 4 SSR recorded after the 2nd dose of RZV in group 1 (day 112), group 3 (day 112) and group 4 (day 56) compared to grade 3 SSR recorded after the 2nd dose RZV with aQIV in group 5
7. SSR events recorded over 7 days after 1st and 2nd doses of RZV given alone compared to co-administration with either COVID-19 vaccine or aQIV
8. Solicited local adverse reactions recorded over 7 days after 1st or 2nd doses of RZV given alone compared to co-administration with either COVID-19 vaccine or aQIV

Qualitative outcomes:
1. Participant acceptance of multiple vaccinations (2 or more) for future routine vaccinations
2. Trial staff perceptions on offering multiple vaccinations (2 or more) for future routine vaccinations

Previous secondary outcome measure:
1. Cell-mediated responses to two doses of RZV, measured using glycoprotein E specific CD4+ cells measured by intracellular cytokine staining 1 month after the second dose, given alone compared to co-administration with Bivalent vaccine with 1st or 2nd dose of RZVA
2. Exploratory evaluation of CD4+ T-cells against COVID-19 using S and N protein-specific T-cells measured by ELISpot after vaccination with RZVor aQIV (CMI cohort)
3. N- N-protein immunoglobulin measured using total antibody against N-protein (total anti-N protein antibody concentration) measured by electrochemiluminescence immunoassay (ECLIA) before and 1 month after the first vaccination in the (exploratory immunology cohort
4. Grade 3 and 4 SSR recorded after 1st RZV dose in group 1 (day 56), group 2 and 5 (day 0) compared to grade 3 SSR recorded after 1st dose of RZV with Bivalent vaccine in group 3 (day 56)
5. Grade 3 and 4 SSR recorded after 1st dose RZV in group 1 (day 56), group 2 and 5 (day 0) compared to grade 3 SSR recorded after 1st dose of RZV with aQIV in group 4 (day 0)
6. Grade 3 and 4 SSR recorded after the 2nd dose of RZV in group 1 (day 112), group 3 (day 112) and group 4 (day 56) compared to grade 3 SSR recorded after the 2nd dose RZV with aQIV in group 5
7. SSR events recorded over 7 days after 1st and 2nd doses of RZV given alone compared to co-administration with either Bivalent vaccine or aQIV
8. Solicited local adverse reactions recorded over 7 days after 1st or 2nd doses of RZV given alone compared to co-administration with either Bivalent vaccine or aQIV

(added 23/11/2023)
Qualitative outcomes:
1. Participant acceptance of multiple vaccinations (2 or more) for future routine vaccinations
2. Trial staff perceptions on offering multiple vaccinations (2 or more) for future routine vaccinations

Completion date
19/11/2025

Eligibility

Key inclusion criteria
Current inclusion criteria as of 23/11/2023:

1. Participants who, in the opinion of the investigator, can and will comply with the requirements of the protocol
2. Written informed consent obtained from the participant prior to any study-specific procedure
3. Adults aged 50 years and over at the time of randomisation
4. Participants must have documented history (e.g. NHS app, GP record) or receiving their initial course (usually two doses) of any type of COVID-19 vaccinaiton, irrespective of the type of COVID-19 vaccine received.
5. Female participants of childbearing potential must be willing to ensure that they or their partner use effective contraception from 1 month prior to first vaccination continuously until 3 months after final vaccination*
*A woman of childbearing potential is defined as a pre-menopausal female who is capable of becoming pregnant

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Previous inclusion criteria:

1. Participants who, in the opinion of the investigator, can and will comply with the requirements of the protocol
2. Written informed consent obtained from the participant prior to any study-specific procedure
3. Adults aged 50 years and over at the time of randomisation
4. Participants must have documented previous COVID-19 vaccination in line with UK recommendations at the time of the study
5. Female participants of childbearing potential must be willing to ensure that they or their partner use effective contraception from 1 month prior to first vaccination continuously until 3 months after final vaccination*
*A woman of childbearing potential is defined as a pre-menopausal female who is capable of becoming pregnant

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
Yes

Age group

Mixed

Lower age limit
50 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
967

Key exclusion criteria
Current participant exclusion criteria as of 22/10/2024:
1. Any clinical condition that in the opinion of the investigator might pose additional risk to the participant due to participation in the study.
2. History of reaction or hypersensitivity likely to be exacerbated by any component of the study intervention including allergic reaction to any component of any of the study vaccines, known reactions related to study vaccines e.g. history of myocarditis, GuillainBarre Syndrome.
3. Unstable medical condition on the day of enrolment as determined by clinical history and examination.
4. Bleeding disorders or continuous use of anticoagulation medicine, such as coumarins and related anticoagulants (i.e., warfarin) or novel oral anticoagulants (i.e. apixaban, rivaroxaban, dabigatran and edoxaban). Use of aspirin is allowed.
5. Any confirmed or suspected immunosuppressive, or immunodeficient condition, based on medical history and physical examination. People living with HIV that is well controlled can be included in the study.* Those with a new diagnosis or an AIDs defining illness in the past 12 months cannot be included.
6. Use of immunosuppressive medication, ongoing, long term or planned, defined as more than 14 days in total of immunosuppressant treatments. For corticosteroids this will mean more than 14 days of prednisolone >20mg/day or equivalent. Use of inhaled, intraarticular and topical steroids is allowed.
7. Use or planned use of long-acting immune modifying drugs in the 12-month period before randomisation (e.g. infliximab).
8. COVID-19 or influenza vaccination 90 days prior to the study vaccination
9. Previous vaccination with a live herpes zoster vaccine within the past 5 years.
10. Administration of monoclonal antibodies (including those targeting SARS CoV2), immunoglobulins and/or blood products during the 3 months before the first dose of the study vaccines, up to 1 month after the last dose or planned during the study period.
11. Planning to or concurrently participate in another interventional clinical study.
12. Pregnancy, lactation or willingness/intention to become pregnant within the study period.
13. Previous participation in the ZosterFluCOV trial.
*Defined as less than 50 copies/ml (convert as needed from IU/ml) on the last two occasions >3 months apart, and a CD4 over 500 when last checked.

Previous participant exclusion criteria as of 23/11/2023:
1. Any clinical condition that in the opinion of the investigator might pose additional risk to the participant due to participation in the study

2. History of reaction or hypersensitivity likely to be exacerbated by any component of the study intervention including allergic reaction to any component of any of the study vaccines, known reactions related to study vaccines e.g. history of myocarditis, Guillain-Barre Syndrome
3. Unstable medical condition on the day of enrolment as determined by clinical history and examination
4. Bleeding disorders
5. Any confirmed or suspected immunosuppressive, or immunodeficient condition, based on medical history and physical examination. People living with HIV that is well controlled can be included in the study.* Those with a new diagnosis or an AIDs defining illness in the past 12 months cannot be included.
6. Use of immunosuppressive medication, ongoing, long term or planned, defined as more than 14 days in total of immunosuppressant treatments. For corticosteroids this will mean more than 14 days of prednisolone >20 mg/day or equivalent. Use of inhaled, intra-articular and topical steroids is allowed.
7. Use or planned use of long-acting immune modifying drugs in the 12-month period before randomisation (e.g. infliximab)
8. COVID-19 or influenza vaccination 90 days prior to study vaccination
9. Previous vaccination with a live herpes zoster vaccine within the past 5 years
10. Administration of monoclonal antibodies (including those targeting SARS-CoV-2), immunoglobulins and/or blood products during the 3 months before the first dose of the study vaccines, up to 1 month after the last dose or planned during the study period
11. Planning to or concurrently participating in another interventional clinical study
12. Pregnancy, lactation or willingness/intention to become pregnant within the study period
13. COVID-19 or flu vaccine within 90 days, any other vaccine within 30 days of study vaccination
*Defined as less than 50 copies/ml (convert as needed from IU/ml) on the last two occasions >3 months apart, and a CD4 over 500 when last checked.

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Previous participant exclusion criteria:
1. Any clinical condition that in the opinion of the investigator might pose additional risk to the participant due to participation in the study
2. History of reaction or hypersensitivity likely to be exacerbated by any component of the study intervention including allergic reaction to any component of any of the study vaccines, known reactions related to study vaccines e.g. history of myocarditis, Guillain-Barre Syndrome
3. Unstable medical condition on the day of enrolment as determined by clinical history and examination
4. Bleeding disorders
5. Any confirmed or suspected immunosuppressive, or immunodeficient condition, based on medical history and physical examination
6. Use of immunosuppressive medication, ongoing, long term or planned, defined as more than 14 days in total of immunosuppressant treatments. For corticosteroids this will mean more than 14 days of prednisolone >20 mg/day or equivalent. Use of inhaled, intra-articular and topical steroids is allowed.
7. Use or planned use of long-acting immune modifying drugs in the 12-month period before randomisation (e.g. infliximab)
8. Planned vaccination within 30 days of study vaccination
9. Previous vaccination with a live herpes zoster vaccine within the past 5 years
10. Administration of monoclonal antibodies (including those targeting SARS-CoV-2), immunoglobulins and/or blood products during the 3 months before the first dose of the study vaccines, up to 1 month after the last dose or planned during the study period
11. Planning to or concurrently participating in another interventional clinical study

12. Pregnancy, lactation or willingness/intention to become pregnant within the study period
13. COVID-19 or flu vaccine within 90 days, any other vaccine within 30 days of study vaccination

Date of first enrolment
01/10/2023

Date of final enrolment
28/02/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University Hospitals Bristol and Weston NHS Foundation Trust
Trust Headquarters
Marlborough Street
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Study participating centre
Guy's and St Thomas' NHS Foundation Trust
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Westminster Bridge Road
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Study participating centre
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Study participating centre
Royal United Hospitals Bath NHS Foundation Trust
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BA1 3NG

Study participating centre
Hull University Teaching Hospitals NHS Trust
Hull Royal Infirmary
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HU3 2JZ

Study participating centre
South Tees Hospitals NHS Foundation Trust
James Cook University Hospital
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TS4 3BW

Study participating centre
Trust Hq Gloucestershire Hospitals NHS Foundation Trust
Alexandra House
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GL53 7AN

Study participating centre
University Hospital Southampton NHS Foundation Trust
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Study participating centre
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168 Locking Road

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BS23 3HQ

Study participating centre
Sheffield Teaching Hospitals NHS Foundation Trust
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England
S5 7AU

Study participating centre
Marine Lake Medical Practice
Marine Lake Health & Wellbeing Ctr
Orrysdale Road
West Kirby
Wirral
England
CH48 5AA

Study participating centre
North Bristol NHS Trust
Southmead Hospital
Southmead Road
Westbury-on-trym
Bristol
England
BS10 5NB

Sponsor information

Organisation
University Hospitals Bristol and Weston NHS Foundation Trust

ROR
https://ror.org/03jzzxg14

Funder(s)

Funder type
Industry

Funder Name
GlaxoSmithKline

Alternative Name(s)
GlaxoSmithKline plc., GSK plc., GlaxoSmithKline plc, GSK

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be published as a supplement to the results publication. Anonymised trial data will only be made available for sharing after the publication of the main results of the trial. Thereafter, individual participant data will be made available for secondary research, conditional on assurance from the secondary researcher that the proposed use of the data is compliant with the MRC Policy on Data Sharing regarding scientific quality, ethical requirements and value for money. A minimum requirement with respect to scientific quality will be a publicly available pre-specified protocol describing the purpose, methods and analysis of the secondary research, e.g., a protocol for a Cochrane systematic review. If participants consent for the storage of samples for future research, a copy of the participant's consent form will be shared with the licenced Research Tissue Bank. If participants consent, local sites will store their contact details so they can be contacted about future studies that may be relevant.

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		04/06/2026	02/11/2026	Yes	No
Basic results			20/02/2026	No	No
HRA research summary			20/09/2023	No	No
Participant information sheet		11/11/2025	11/11/2025	No	Yes
Plain English results			18/11/2026	No	Yes
Protocol file	version 4.0	18/09/2023	23/11/2023	No	No
Protocol file	version 9.0	17/12/2024	03/03/2025	No	No

Study website	11/11/2025	11/11/2025	No	Yes