

Optimizing herpes zoster vaccination in immunosuppressed patients with inflammatory bowel disease

Submission date 24/01/2026	Recruitment status Recruiting	☒ Prospectively registered ☐ Protocol
Registration date 26/05/2026	Overall study status Ongoing	☐ Statistical analysis plan ☐ Results
Last Edited 05/10/2026	Condition category Digestive System	☐ Individual participant data ☒ Record updated in last year

Plain English summary of protocol

Background and study aims

Inflammatory bowel disease (IBD) is a lifelong condition where the body's immune system attacks the gut. This can lead to people with IBD (including Ulcerative colitis and Crohn's disease) experiencing stomach pain, bleeding, and diarrhoea.

People with IBD take regular medications such as JAK-inhibitors. These medications work by lowering activity in the immune system. But this means that people with IBD have more chance of catching infections as the body finds it harder to fight them off.

If you are taking a JAK-inhibitor, you are at particularly high risk of shingles. Shingles can cause a painful skin rash similar to chicken pox. Adults who have had chicken pox can get shingles. One way for adults with IBD to avoid shingles is to have the shingles vaccination. However, medications such as JAK-inhibitors have been shown to make some vaccines not work as well. In this study, we will see if pausing JAK-inhibitor medication for a short time helps the shingles vaccination to work better.

Who can participate?

Adults with IBD who are stable on JAK-inhibitor medication and have had chicken pox will be invited to take part.

What does the study involve?

Participants who agree to take part in this study will be put into one of two groups – the chance of a being in either group is like flipping a coin.

The first group will take their JAK-inhibitor medication as normal and receive two doses of the shingles vaccine. The other group will pause their IBD medication for seven days at a time while they receive two doses of the shingles vaccine. Researchers will then compare results from both groups.

This study will take place at around five UK hospitals. Participants will come to site five times over 14 months with follow-up telephone calls in between.

What are the possible benefits and risks of participating?

It is not known if there will be any benefits from joining this study. The researchers are trying to

see if pausing JAK-inhibitor medication improves the response to the shingles vaccine. Therefore, involvement in this study could improve the long-term outcomes for people living with IBD and patients with other diseases, such as arthritis, treated with JAK-inhibitors.

Shingrix:

In rare cases (1 in 1,000 doses) Shingrix can cause allergic reactions including rash, hives, swelling of the face, tongue or throat which may cause difficulty in swallowing or breathing. Serious adverse reaction to a previous vaccination is a trial exclusion, and prior to consent the PI will check vaccine history thoroughly for each individual. If the PI has any queries about previous reactions or symptoms, these can be discussed with the trial Chief Investigator (CI) or research physicians within the research team.

Some participants might experience mild symptoms during and after each vaccination dose, including a numb or swollen arm at the vaccine site. Aches and any other mild flu-like symptoms normally clear after 3 days. Participants will be asked to contact the site team if they are feeling very unwell after the vaccination dose, or if symptoms persist.

Pregnancy:

Females who are pregnant, or planning to become pregnant during the course of the trial (14 months) will be excluded prior to consent.

If a participant is found to be pregnant after the first dose of vaccine then the second dose will not be given. The participant will only be considered for safety follow ups. If a participant is found to be pregnant after second dose of vaccine then we will monitor the patient for safety.

Blood collection:

Blood tests may cause some redness, swelling of the vein, infection or fainting and this is explained to participant in the PIS.

Where is the study run from?
Imperial College London (UK)

When is the study starting and how long is it expected to run for?
July 2026 to April 2029

Who is funding the study?
GlaxoSmithKline (UK)

Who is the main contact?
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Contact information

Type(s)

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Additional identifiers

Integrated Research Application System (IRAS)

1013274

Sponsor's protocol code number

172153

Study information

Scientific Title

Optimizing Herpes Zoster Vaccination in Immunosuppressed patients with Inflammatory Bowel Disease

Acronym

OVATION-IBD

Study objectives

The primary objective of this study is to assess the impact of pausing JAK-inhibitor therapy on peak vaccine-induced humoral immunogenicity at days 30-48 (post second vaccine dose) during Shingrix immunisation.

Secondary objectives:

1. To assess the impact of pausing JAK-inhibitor therapy on short (30-48 days post second vaccine dose) and long term (330-425 days post second vaccine dose) rates of vaccine response rate (VRR) to Shingrix immunisation.
2. To assess the impact of pausing JAK-inhibitor therapy on peak vaccine-induced cell-mediated immunogenicity (30-48 days post second vaccine dose) during Shingrix immunisation.
3. To assess the impact of pausing JAK-inhibitor therapy on durability of vaccine-induced humoral and cell-mediated immunogenicity (330-425 days post second vaccine dose) during Shingrix immunisation.
4. To assess the impact of pausing JAK-inhibitor therapy on fold increase in vaccine-induced humoral immunogenicity during Shingrix vaccination.
5. To assess the safety of pausing JAK-inhibitor therapy for IBD during vaccination against Herpes Zoster.
6. To assess the reactogenicity of Shingrix vaccination in patients with IBD.

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 03/03/2026, North East - Newcastle & North Tyneside 1 Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; no telephone number provided; newcastlenorthtyneside1.rec@hra.nhs.uk), ref: 26/NE/0029

Primary study design

Interventional

Allocation

Randomized controlled trial

Masking

Open (masking not used)

Control

Active

Assignment

Parallel

Purpose

Prophylaxis

Study type(s)

Efficacy, Safety, Other

Health condition(s) or problem(s) studied

Inflammatory bowel disease

Interventions

Following a baseline visit, participants will be instructed to either continue or pause JAK-inhibitor therapy according to their study arm allocation.

The experimental intervention group will be asked to pause JAK-inhibitor therapy for seven days around Shingrix vaccination (3 days before and 3 days after) each vaccine dose. The control intervention group will be asked to continue JAK-inhibitor therapy as normal throughout the vaccination process. All participants will receive two doses of Shingrix vaccine 6-8 weeks apart according to the vaccine license. Participants will be followed up after each vaccine dose to check for IBD flares and other adverse events. Blood samples will be collected at baseline and at 30-48 days and 335-425 days after the second vaccine dose. Study follow up ends at 52 weeks after the second vaccine dose (approximately 61 weeks after study entry). Randomisation is parallel-group and open-label.

Intervention Type

Drug

Phase

Phase IV

Drug/device/biological/vaccine name(s)

Shingrix [Varicella Zoster Virus glycoprotein E antigen]

Primary outcome(s)

The geometric mean concentration of anti-glycoprotein E antibody at days 30-48 (post second vaccine dose) in IBD patients pausing JAK-inhibitor therapy in comparison with patients continuing JAK-inhibitor therapy.

Key secondary outcome(s)

Immunogenicity endpoints:

1. The vaccine response rate (VRR) of participants in the JAK-inhibitor therapy pausing arm (defined as 4-fold increase in anti-glycoprotein E antibody) compared to the control arm at 30-48 days post second vaccine dose.
2. The VRR in the JAK-inhibitor therapy pausing arm (defined as 4-fold increase in anti-glycoprotein E antibody) compared to the control arm at 335-425 days post second vaccine dose.
3. The geometric mean concentration of anti-glycoprotein E antibody at 335 to 425 days (post second vaccine dose) in IBD patients pausing JAK-inhibitor therapy in comparison with patients continuing JAK-inhibitor therapy.
4. T cell responses measured by flow cytometry at days 30-48 (post second vaccine dose) in IBD patients pausing JAK-inhibitor therapy in comparison with patients continuing JAK-inhibitor therapy.
5. T cell responses measured by flow cytometry at 335-425 days (post second vaccine dose) in IBD patients pausing JAK-inhibitor therapy in comparison with patients continuing JAK-inhibitor therapy.

Safety/Reactogenicity endpoints :

1. The rate of adverse events in IBD patients pausing JAK-inhibitor therapy and in patients continuing JAK-inhibitor therapy.
2. The rate of serious adverse events in IBD patients pausing JAK-inhibitor therapy and in patients continuing JAK-inhibitor therapy.

3. The rate of IBD flares in patients pausing JAK-inhibitor therapy and in patients continuing JAK-inhibitor therapy.
4. The rate of major IBD related adverse events (hospitalisations, IBD surgery including colectomy).
5. The rate of vaccine reactogenicity including mild (e.g. local injection site reaction) and severe (e.g. anaphylaxis) reactions to Shingrix vaccination.

Time frame for safety endpoints:

- for a solicited symptom timeframe is the day of vaccination and 6 additional days
- for an unsolicited symptom timeframe is the day of vaccination and 29 additional days
- for a SAE/pIMD and specific adverse event timeframe is the day of vaccination up to 12 months post last dose.

Completion date

30/04/2029

Eligibility

Key inclusion criteria

1. Adults (aged ≥ 18 years).
2. History of primary varicella infection (chicken pox) confirmed by a previous history of positive varicella zoster virus (VZV) Immunoglobulin G antibody or history of chicken pox.
3. Established diagnosis of CD or UC or IBD-unclassified using standard definitions of IBD.
4. Established on JAK-inhibitor therapy (either upadacitinib, tofacitinib or filgotinib) for at least 12 weeks.
5. IBD in stable remission* and able to temporarily pause JAK-inhibitor therapy for two periods of 7 days in the opinion of patients' hospital team without the risk of substantial increase in disease activity.
6. Able to give informed consent.
7. Willing and able to meet all protocol requirements and procedures (including pausing of JAK-inhibitor therapy).

*Definition of IBD in stable remission:

I. Stable remission defined as having completed 8 weeks induction with JAK-inhibitor therapy, maintained for a minimum of an additional 4 weeks, according to retrospective assessment of the patients' medical files. To be confirmed by a faecal calprotectin measurement $<250 \mu\text{g/g}$ and /or colonoscopy showing no active inflammation after the end of induction and within 4 weeks of screening.

II. The following clinical criteria will apply at screening:

o UC: PRO2 ≤ 1 with Rectal Bleeding score = 0 and Stool Frequency score ≤ 1 .

o CD: A modified\$ Harvey Bradshaw Index (HBI) score <5 .

^Calprotectin result signifying remission is assay specific. $<250 \mu\text{g/g}$ used here as indicative of assay used at Imperial College Healthcare NHS Trust.

\$HBI without the 'abdominal mass' question.

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

18 Years

Upper age limit

99 Years

Sex

All

Total final enrolment

0

Key exclusion criteria

1. Previous receipt of any HZ vaccine including Shingrix.
2. History of a confirmed anaphylactic reaction to any component of the vaccine.
3. History of herpes zoster or post herpetic neuralgia within the past year.
4. Primary reason for JAK-inhibitor therapy is a non-IBD immune mediated inflammatory disorder (e.g. for rheumatoid arthritis or psoriasis). Patients who are receiving JAK-inhibitor for IBD and also have other immune mediated inflammatory disorders may be included.
5. Currently receiving other immunosuppressive drug in addition to JAK-inhibitor therapy (N.B. 5-ASA therapies are not considered immunosuppressive).

List to include:

- Adalimumab
- Infliximab
- golimumab
- certolizumab
- vedolizumab
- ustekinumab
- Risankizumab
- mirikizumab
- guselkumab
- etrasimod
- ozanimod
- mycophenolate
- tacrolimus
- thalidomide
- ciclosporin.
- cyclophosphamide.
- hydroxychloroquine.
- leflunomide.
- methotrexate.

6. Current use of oral or intravenous steroids (dose equivalent to >Prednisolone 10mg od) within 30 days.
7. Patient has received polyclonal immunoglobulin therapy or blood products within the last year.
8. Receiving cancer chemotherapy or immunotherapy within last 6 months.
9. Patient is currently pregnant or planning pregnancy, or currently breastfeeding.
10. Already participating in a CTIMP (clinical trial of an investigational medicinal product).

Date of first enrolment

31/07/2026

Date of final enrolment

02/07/2027

Locations

Countries of recruitment

United Kingdom

England

Scotland

Study participating centre

Imperial College Healthcare NHS Trust

Hammersmith Hospital

Du Cane Road

London

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W12 0HS

Study participating centre

Hull University Teaching Hospitals NHS Trust

Hull Royal Infirmary

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Study participating centre

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Southampton General Hospital

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Study participating centre

Royal Devon University Healthcare NHS Foundation Trust

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Study participating centre**Lucs Western General Hospital**

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Study participating centre**University Hospitals Birmingham NHS Foundation Trust**

Queen Elizabeth Hospital
Mindelsohn Way
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B15 2GW

Sponsor information

Organisation

Imperial College London

ROR

<https://ror.org/041kmwe10>

Funder(s)

Funder type**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

Requests will be evaluated on a case-by-case basis and only where the adequate consent and safeguards are in line with GDPR and data processing agreements.

IPD sharing plan summary

Available on request