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Immune response to Shingrix vaccination in patients with chronic lymphocytic leukemia or Waldenstrom macroglobulinemia while undergoing treatment with BTK inhibitors

Submission date
15/11/2023

Recruitment status
No longer recruiting

Registration date
16/11/2023

Overall study status
Completed

Last Edited
17/11/2023

Condition category
Cancer

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

Plain English summary of protocol

Background and study aims
The blood cell cancers chronic lymphocytic leukemia (CLL) and Waldenstrom macroglobulinemia (WM) are known risk factors for zoster reactivation, commonly called shingles. Shingles is a viral infection that causes a painful rash. Although a recently FDA-approved herpes zoster vaccine (Shingrix) is currently being offered to these populations, no study has specifically evaluated the vaccine response in patients while on treatment with single-agent BTK inhibitors, the current standard therapy for this group. The aim of this study is to evaluate the immune response, through a blood test, to the Shingrix vaccine in these patients.

Who can participate?
Patients with CLL or WM who are at least 50 years old and undergoing first-line treatment with a BTK inhibitor.

What does the study involve?
Participants will receive two doses of the Shingrix vaccine administered as an injection into the muscle in their upper arm. The second dose of vaccine will be administered about 2 months after the first dose. Blood samples will be collected before the first dose of vaccine, about 4 weeks and 24 months after the second dose of vaccine.

What are the possible benefits and risks of participating?
Potential benefits are getting an FDA-approved zoster vaccine. Potential risks associated with blood draws include lightheadedness, bruising at the site of the needle stick and infection. Common side effects of the Shingrix vaccine include pain, redness and swelling at the injection site, muscle pain, tiredness, headache, shivering, fever and upset stomach.

Where is the study run from?
University of Rochester (USA)

When is the study starting and how long is it expected to run for?
June 2018 to August 2022

Who is funding the study?
1. University of Rochester (USA)
2. GlaxoSmithKline Biologicals (Belgium)

Who is the main contact?
Dr Michael Brady, Michael_Brady@urmc.rochester.edu

Contact information

Type(s)
Public, Scientific

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Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number

NCT03771157

Secondary identifying numbers
RSRB00003228

Study information

Scientific Title
Serologic response to a new recombinant, adjuvanted herpes zoster vaccine in patients with chronic lymphocytic leukemia and Waldenstrom macroglobulinemia treated with first-line BTK inhibitors

Study objectives
Patients with chronic lymphocytic leukemia (CLL) or Waldenstrom macroglobulinemia (WM) undergoing first-line treatment with BTK inhibitors will elicit short-term and long-term immune response to the Shingrix varicella zoster vaccine.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 03/01/2019, Research Subjects Review Board (601 Elmwood Ave, Rochester, 14642, United States of America; +1 (0)585 273 4576; michelle_giglio@urmc.rochester.edu), ref: RSRB00003228

Study design
Single-center interventional one-arm pilot study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
University/medical school/dental school

Study type(s)
Other

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Chronic lymphocytic leukemia or Waldenstrom macroglobulinemia

Interventions
Participants will receive two doses of the Shingrix vaccine administered as an injection into the muscle in their upper arm. The second dose of vaccine will be administered about 2 months after

the first dose. Blood samples will be collected before the first dose of vaccine, about 4 weeks and 24 months after the second dose of vaccine.

Intervention Type
Biological/Vaccine

Pharmaceutical study type(s)
Immunological Response

Phase
Phase I

Drug/device/biological/vaccine name(s)
Recombinant Varicella Zoster Glycoprotein E (Shingrix)

Primary outcome measure
Vaccine response at 4 weeks post-vaccination, as determined by serum antibody levels to the varicella virus glycoprotein E subunit (anti-gE) measured using ELISA

Secondary outcome measures
Vaccine response at 24 months post-vaccination, as determined by serum antibody levels to the varicella virus glycoprotein E subunit (anti-gE) measured using ELISA

Overall study start date
20/06/2018

Completion date
03/08/2022

Eligibility

Key inclusion criteria
1. Patients diagnosed with chronic lymphocytic leukemia (CLL) OR Waldenström macroglobulinemia (WM)
2. 50 years of age or older
3. Receiving first-line treatment with BTK inhibitor for at least 3 months; prior treatment with single-agent rituximab is permitted if the last dose was administered more than 1 year ago
4. Have at least a 1-year life expectancy
5. Have a history of varicella (chickenpox) OR lived in the US or any endemic country for >30 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
50 Years

Sex

Both

Target number of participants
33

Total final enrolment
32

Key exclusion criteria
1. Known hypersensitivity to a vaccine component
2. Herpes zoster reactivation within the past year
3. Received or were scheduled to receive a live virus vaccine in the period from 4 weeks prior to Dose 1 through 28 days post-second dose
4. Received or were scheduled to receive an inactivated vaccine in the period ranging from 7 days prior to Dose 1 through 7 days post-second dose
5. Are unable to give informed consent;
6. An absolute lymphocyte count greater than 20,000 x 10e9/L
7. Receiving treatment for CLL or WM with an additional agent other than a BTK inhibitor
8. Rituximab treatment less than one year prior to study start
9. Prior chemotherapy

Date of first enrolment
01/02/2019

Date of final enrolment
18/06/2019

Locations

Countries of recruitment
United States of America

Study participating centre
University of Rochester Medical Center, Wilmot Cancer Institute
601 Elmwood Ave
Rochester
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Sponsor information

Organisation
University of Rochester

Sponsor details

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Sponsor type
University/education

Website
https://www.rochester.edu

ROR
https://ror.org/022kthw22

Funder(s)

Funder type
University/education

Funder Name
University of Rochester

Alternative Name(s)
U of R, U of Rochester, Universitas Rocestriensis, UR

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United States of America

Funder Name
GlaxoSmithKline Biologicals

Alternative Name(s)
GSK Belgium, GlaxoSmithKline Biologicals SA, GlaxoSmithKline Biologicals SAS, GlaxoSmithKline (GSK) Biologicals, GSK Biologicals, GSK

Funding Body Type

Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
Belgium

Results and Publications

Publication and dissemination plan
Study results were published in 2023.

Intention to publish date

Individual participant data (IPD) sharing plan
Data generated from this study will be available upon reasonable request from Dr Michael Brady (michael_brady@urmc.rochester.edu).
Summary-level participant demographic data will be shared upon request, individual participant demographic data will not be shared due to the limited number of participants. Raw ELISA data collected from samples at baseline, 4 weeks and 24 months post-vaccination with associated disease type will be shared. Data are available now. All participants were consented prior to study activities. All data is anonymous, patient identifiable information will not be shared.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		23/07/2023	16/11/2023	Yes	No
Basic results			17/11/2023	No	No