



## Brief Information Leaflet for a Clinical Trial

### Shingles vaccine in people who have previously had Shingles

#### BRIEF INFORMATION ABOUT A NEW RESEARCH STUDY:

We would like to invite you to take part in a research study to learn more how the current Shingles vaccine affects people that have previously had Shingles

#### HOW DO I TAKE PART?

If you would like to take part or you have any queries about the clinical research study, please contact the team on:

**Lyn Glover**  
**lyn.glover1@nhs.net**  
**0161 248 6644**

Doctor **Rebecca Winter at Bodey Medical Centre** is looking for adults aged over 50 years who have had a previous shingles episode to participate in a GlaxoSmithKline sponsored research study.

This study has been reviewed and approved for conduct in the NHS by the East Midlands - Leicester South National Research Ethics Committee.  
(Reference 2016-000744-34)

#### REASON FOR THE RESEARCH STUDY

The study will follow adults more than 50 years old with shingles. We want to see if you have another shingles attack with or without the study vaccine.

This research will also study vaccine safety and how the vaccine works in the people who get shingles.

## WHAT IS A RESEARCH STUDY?

Many different research studies must be done to thoroughly test a vaccine before it can be given to the public. National health agencies look at the results of these studies to decide if they will approve the vaccine for general use. All the vaccines you have ever been given in your life have been through this same process.

## EXPENSES AND PAYMENTS

We will reimburse you for time, travel and inconvenience.

## THE DISEASE AND VACCINE BEING STUDIED

This research study will test the HZ/su vaccine (Tradename *Shingrix*), made to protect against shingles. It has been approved for use in Europe.

So far, the study vaccine has been studied in almost 30,000 people aged 50 years and older in previous research studies. Millions more have received the vaccine in countries where it is already approved.

This research study is done to learn more about how the vaccine changes your chance of having another shingles attack, how people react to the vaccine shot, how the vaccine works on your immune system and how safe it is.

## BENEFITS OF JOINING THIS RESEARCH STUDY?

There is no guaranteed benefit from taking part in the study. The vaccine may or may not protect you against a future shingles attack, BUT by participating, you will help us to learn more about the vaccine, how the vaccine may work in your body to prevent shingles attacks, and the disease, shingles, itself.

There is no guaranteed benefit from taking part in the study. The vaccine may or may not protect you against a future shingles attack, BUT by participating, you will help us to learn more about the vaccine, how the vaccine may work in your body to prevent shingles attacks, and the disease, shingles, itself.

## WHAT THE STUDY WILL INVOLVE?

Participants will come to the clinic at least 3 times and will have monthly telephone call follow-up contacts for at least 2 years from the second vaccine injection. For some participants the study could last up to approximately 4 years.

Participants entering the study will get 2 doses of either the vaccine or placebo (dummy vaccine) given into the arm muscle. The first dose is given at Visit 1 and the second dose is given 2 months after the first.

Blood samples will be taken from participants during the first three visits for measuring the immune response.

If participants develop shingles while on study, you will be invited to make extra trips to the clinic and to have extra telephone contacts for additional assessments.

