ATHENA STUDY PATIENT SUMMARY

Why are you asking me to take part in a research study?

Because you are an **adult 50 years or older** who has just been **diagnosed with shingles**

AND

your clinician says you are eligible to take part in a research study called ATHENA (Amitriptyline for the prevention of post-herpetic neuralgia).

Why is this study needed?

Some people can have nerve pain in the area of the shingles rash, months after the rash has gone. This is called “post-herpetic neuralgia”.

- We currently do not have any treatments that prevent this.
- We want to find out if taking a low dose of a tablet called amitriptyline may help prevent it.

The only way to find out if amitriptyline helps is by doing a clinical trial.

What is involved in taking part in the study?

If you agree to take part:

- You will be asked to take tablets nightly for up to 10 weeks.
- Over the following 3 months, you will be asked to complete four questionnaires, each 5-10 minutes long.

All of your other medical care will be the same.

What do I do next if I am interested?

There is more information about the medication below, but if you are interested, your clinician will pass your details onto the research team, who will:

- Send you more detailed information about the study (the Participant Information Leaflet) and
- Arrange a time to speak with you, to answer any questions you have about the study and, if you are happy, to sign you up to the study.

Tell me more about the medication

Amitriptyline has been used since the 1960s, so it is not a new medication.

- Nowadays it is used at low dose (10-30 mg) to **treat** problems like nerve pain.
- In this study, we are trying to find out whether low dose amitriptyline can actually **prevent** the nerve pain caused by shingles.

You will be given amitriptyline or placebo ("dummy") pills to take nightly for up to 70 days.

- A process called "randomisation" (a bit like rolling dice) will decide which group you go into. This will ensure that the results cannot be affected by anyone's beliefs about amitriptyline.
- Like all tablets, even at low dose some people may get side-effects. We will monitor these and you will be able to discuss any problems with the study team or your clinician.
- In an emergency, we can quickly tell you which group you are in and whether you are taking amitriptyline or a placebo.

If you are unable to take the medication or you change your mind, you can stop taking the tablets and/or withdrawal from the study at any time.

What about other tablets or medical problems?

Your clinician will only put you forward for the study if it is safe to take amitriptyline alongside any other medicines or medical problems that you may have.

- You can continue taking all your other current medications as normal throughout the study.
- Your clinician can prescribe most other medications normally if you need them.
- You can continue to have any vaccinations that you require as normal.

However, for the ~10 weeks that you are taking the study tablets, your clinician will not be able to give you additional amitriptyline at the same time.

For further information

Ask your participating GP surgery or contact the ATHENA research team directly by email (athena-study@bristol.ac.uk) or phone: 0117 331 4532

If you are interested you will be sent a patient information leaflet by the study team, but you can access this yourself in the meantime, by visiting: www.bristol.ac.uk/athena-study (Patient information leaflet is under '**P**rotocol and information' tab).