Summary of Results for Laypersons

What was the Study Called?

Tolerability of QUTENZA™ When Applied After Pre-treatment With Lidocaine or Tramadol in Subjects With Peripheral Neuropathic Pain - A Randomized, Multi-center, Assessor-blinded Study. This is also known as the LIFT study.

Why was this Study Needed?

The peripheral nerves are the nerves outside of the spinal cord and brain. Peripheral neuropathic pain is caused by damage to these nerves (called "peripheral nerve damage"). This pain usually occurs in the hands and feet but can also occur in other body locations. The causes of common types of peripheral nerve damage are as follows:

- The chickenpox (herpes zoster) virus can cause a painful rash with blisters that break open and crust over ("shingles"). Shingles can result in pain even after the rash is gone.
- The cause of painful diabetic peripheral neuropathy, or diabetic nerve pain, is chronic high blood sugar and diabetes.
- The cause of human immunodeficiency virus (HIV)-associated neuropathy is an infection with that virus.
- The cause of post-traumatic nerve injury is surgery or trauma.

There are already medicines for the treatment of peripheral neuropathic pain. They include lidocaine cream to put on the skin and tramadol capsules to take by mouth. Those medicines may cause unwanted effects or may not work in all patients. The capsaicin 8% patch ("capsaicin patch") delivers capsaicin into the skin to the nerves that cause pain. The high doses of capsaicin in the patch overstimulate these nerves. The nerves then become less sensitive and can no longer produce pain signals.

This was a study of patients with postherpetic neuralgia or post-traumatic nerve injury. These patients took a pretreatment for their pain (lidocaine cream or tramadol capsules). Next, they received capsaicin patches. The study looked at the proportion of patients who could bear the capsaicin patch for at least 90% of the time it was supposed to stay on. It was also important to find out what unwanted effects these patients had from the capsaicin patch if applied after a pain pretreatment medicine.

This study for the capsaicin patch (also known as Qutenza®) took place at 19 clinics in Belgium, Czech Republic, Denmark, Ireland, Norway, Slovakia and the UK. The study took place from July 2011 to April 2012. When the study ended, the sponsor (Astellas) reviewed all the study information and created a report of the results. This is a summary of that report.

What Kind of Study was This and Who Took Part in it?

All patients in this study knew which pain pretreatment they took (lidocaine cream or tramadol capsules). They also knew that they received capsaicin patches. The study doctors who did the clinical tests did not know the treatments of the patients.

Men and women who had never used Qutenza patches took part in the study. They could be in the study if:

- They were between 18 and 90 years old and in good health according to the study doctor.
- They had postherpetic neuralgia or post-traumatic nerve injury for at least 3 months.
- Their pain was at least 4 on a scale of zero ("no pain") to 10 ("pain as bad as you can imagine") before the study start. This pain was the average pain over the last 24 hours.
- The skin of the painful spots was dry and was not damaged or irritated.
- Women who could have children used reliable birth control methods.

Patients could not take part in the study if:

- They had significant pain. This pain was not caused by postherpetic neuralgia or by post-traumatic nerve injury.
- They had chronic pain in an arm, leg, hand or foot, usually after that limb had been injured.
- Their painful spots were only on their face, above their hairline, on their feet and/or close to tissues that secrete mucus.
- They had, or used to have, type 1 or type 2 diabetes. Diabetes is a disease in which the blood sugar level is too high. The sugar comes from consumed foods. Insulin is a hormone that helps the sugar move from the blood into the cells. The sugar is energy for the cells. In type 1 diabetes, the body does not make insulin. In type 2 diabetes, the body does not make or use insulin well.
- They had cancer or had received cancer treatment within 1 year before study visit 2.
- They had a heart condition within 6 months before study visit 2 that required treatment.

The study had 3 visits. At visit 1, patients were checked to see if they could be in the study. At visit 2, patients who could stay in the study were picked for 1 of the following 2 pain pretreatments by chance alone:

- Lidocaine 4% cream was put on the skin. One hour later, the cream was removed and the patients received a single patch treatment.
- Patients took tramadol capsules (50 mg) by mouth. Thirty minutes later, they received a single patch treatment.

All patients received a single treatment with capsaicin patches. The capsaicin patches were put on up to 4 painful spots. The capsaicin patches were removed from the feet after 30 minutes. The capsaicin patches were removed from other body locations after 60 minutes. After 7 days, the patients returned to the clinic for a check-up (visit 3). Visit 3 was the last study visit.

A total of 122 patients were in this study and took study treatment.

	Number of Patients (out of 122 patients)
Age Group	
Aged between 18 and 88 years	122
Sex	
Men	52
Women	70
Clinic Location	
EU Countries	109
Belgium	20
Czech Republic	21
Denmark	16
Ireland	13
Slovakia	15
The UK	24
Outside EU	13
Norway	13

What Were the Study Results?

This was a study of patients with postherpetic neuralgia or post-traumatic nerve injury. They had a pretreatment for their pain (lidocaine cream or tramadol capsules). Next, they received capsaicin patches. The study looked at the proportion of patients who could bear the capsaicin patch for at least 90% of the time it was supposed to stay on. This proportion was similar between the 2 pain pretreatments. It was 98% for patients with the lidocaine pretreatment. It was 100% for patients with the tramadol pretreatment.

What Adverse Reactions did Patients Have?

A lot of research is needed to know whether a medicine causes a medical problem. So when new medicines are being studied researchers keep track of all medical problems that patients have while they are in the study. These medical problems are called “adverse events” and are recorded whether or not they might be caused by the treatment taken. An “adverse reaction” is any medical problem or “adverse event” that is judged by the study doctor to be possibly caused by a medicine or treatment used in the study.

The table below shows the most common adverse reactions experienced by patients. They had the adverse reactions while or after they had at least 1 capsaicin patch applied. The most common adverse reactions were pain where the capsaicin patch was applied; superficial reddening of the skin at a location that was not specified or where the study patch was applied; and pain. For each of these adverse reactions, the number of patients was similar between the 2 groups.

Adverse Reaction	Capsaicin Patch After Pretreatment With Lidocaine Cream (out of 61 patients)	Capsaicin Patch After Pretreatment With Tramadol Capsules (out of 61 patients)
Pain where the study patch was applied	37 (60.7%)	34 (55.7%)
Superficial reddening of the skin (location not specified)	20 (32.8%)	19 (31.1%)
Superficial reddening of the skin where the study patch was applied	13 (21.3%)	10 (16.4%)
Pain	8 (13.1%)	5 (8.2%)

An adverse reaction is considered "serious" when it is life-threatening, causes lasting problems or needs hospital care. None of the patients had this reaction after pretreatment with lidocaine cream or tramadol capsules. Two patients experienced a serious adverse reaction while they had a capsaicin patch applied. One of the 2 patients had high blood pressure both during and after the patch application. The other patient had the capsaicin patch applied to the foot for 60 minutes. The allowed time for applying a Qutenza patch to the feet is 30 minutes. The patch application for 60 minutes was an overdose. This was reported as a serious adverse reaction.

None of the patients died during the study.

Where Can I Learn More About This Study?

Astellas may perform additional studies to better understand capsaicin patches.

This summary of the clinical study results is available online at http://www.astellasclinicalstudyresults.com. Please remember that researchers look at the results of many studies to find out how well medicines work and which adverse reactions they might cause. If you have questions about capsaicin patches, please discuss these with your doctor.

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