Summary of Results for Laypersons

What was the Study Called?

A Phase 3b, Open-label, Parallel-group, Randomized, Multicenter Study to Assess Regadenoson Administration Following an Inadequate Exercise Stress Test as Compared to Regadenoson Alone For Myocardial Perfusion Imaging (MPI) Using Single Photon Emission Computed Tomography (SPECT). This study was also called the EXErcise to Regadenoson in Recovery Trial (EXERRT).

Why was this Study Needed?

Regadenoson (previously called CVT3146) is a medicine that relaxes and widens the blood vessels of the heart and is commonly used in pharmacologic stress testing. Pharmacologic stress testing is a diagnostic procedure in which stress on the heart is induced by medicines (such as regadenoson) instead of exercise. In this study, regadenoson was administered to patients before doing a single photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI) scan. This type of scan allows the doctor to see how well blood flows through a patient's heart muscle. It can show areas of the heart muscle that are not getting enough blood flow. This test is often called a nuclear stress test. It can also show how well the heart muscle is pumping.

A SPECT MPI scan is used in patients with chest discomfort to see if the discomfort comes from lack of blood flow to the heart muscle caused by narrowed or blocked heart vessels (angina). This scan also shows the doctor if heart vessels are blocked and if the patient has had a heart attack in the past.

To test the heart, it is necessary to get more blood flowing to the heart. This can be done by walking on a treadmill. This test is known as an exercise stress test. People who are not able to complete an exercise stress test may not be able to achieve a high enough heart rate needed for a SPECT MPI scan. This study was done to find out if regadenoson administered to patients following inadequate exercise (i.e., patients who tried to exercise but did not exercise enough) had an effect on the results of a SPECT MPI scan.

The main question this study helped answer was if the results of the SPECT MPI scan using regadenoson following inadequate exercise were the same as in patients who received regadenoson without exercising. Also, it was important to find out what unwanted effects might occur.

This study took place at 49 clinics in the United States, Argentina and Peru between June 2012 and December 2014. 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?

This was an "open-label" study. All patients knew that they were receiving regadenoson as a single injection into a vein in their arm.

Both men and women took part in the study. They were all over 18 years old. To be included in the study, patients had to be referred for an exercise stress test or a pharmacological stress SPECT MPI for the evaluation of coronary artery disease (CAD). Patients also had to have signs and symptoms of CAD as determined by the study doctor.

At visit 1, all patients had a SPECT MPI performed without exercise or regadenoson (this was called the "baseline SPECT MPI"). At visit 2, patients were placed into 1 of 2 treatment groups by chance alone. Patients in both groups underwent an exercise stress test and were unable to achieve a high enough heart rate needed to show enough stress on the heart to do a SPECT MPI test. Patients in group 1 (called the "exercise + regadenoson" group) were given regadenoson 3 minutes following exercise and then had a SPECT MPI performed. Patients in group 2 (called the "regadenoson alone" group) rested for 1 hour after exercise and were then given regadenoson followed by a SPECT MPI scan. Patients then went home and returned to the study clinic within 2 weeks. At visit 3, all patients were given regadenoson without exercise followed by a SPECT MPI scan.

A total of 1147 patients were enrolled in the study. Of the 1147 patients, 1142 received at least 1 dose of regadenoson and are listed below by treatment group.

- Group 1: (exercise + regadenoson): 575 patients
- Group 2 (regadenoson alone): 567 patients

Information on the 1142 patients is included in the table below.

	Number of Patients
Age Group	
Aged 18 to 64 years	684
Aged 65 to 74 years	294
Aged 75 years and older	164
Men	669
Women	473
EU Countries	0
Outside EU	1142

What Were the Study Results?

Results from the study showed that exercise did not have an effect on the results of the SPECT MPI scan. The results of the SPECT MPI scan were similar in patients who were given regadenoson 3 minutes after exercise compared to patients given regadenoson 1 hour after exercise. Regadenoson was generally safe and well tolerated with or without association with exercise.

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 greater than 5% of patients while taking part in this study. Information on the 1142 patients who received at least 1 dose of study medicine is included in the table below. The adverse reactions were reported during the 24 hours following the time of administration of regadenoson at visit 2 (MPI 1) and visit 3 (MPI 2).

	Group 1		**Group 2**	
Adverse Reaction	**Visit 2 Stress MPI 1 Exercise + Regadenoson Patients (out of 575)**	**Visit 3 Stress MPI 2 Regadenoson Alone Patients (out of 544)**	**Visit 2 Stress MPI 1 Regadenoson Alone Patients (out of 567)**	**Visit 3 Stress MPI 2 Regadenoson Alone Patients (out of 548)**
Upper belly pain	31	35	34	34
Nausea or urge to vomit	40	43	43	40
Chest discomfort	37	32	53	42
Dizziness (or sensation of lightheadedness, unsteadiness, or giddiness)	100	74	86	77
Taste changes	16	27	25	21
Headache or head pain	82	99	126	115
Shortness of breath	134	121	159	150
Sudden reddening of the face and/or neck	47	77	77	68

An adverse reaction is considered "serious" when it is life threatening, causes lasting problems, or needs hospital care. Two patients in group 1 experienced a serious adverse reaction. No deaths were reported during the study.

Where Can I Learn More About This Study?

After evaluating the results of this clinical study Astellas may perform additional studies to better understand regadenoson.

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 events and reactions they might cause. If you have questions about regadenoson, please discuss these with your doctor.

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