IRIS Trial

Insulin Resistance Intervention after Stroke

A Cooperative Program of the National Institute of Neurological Diseases and Stroke (A Division of the National Institutes of Health) and over 60 health centers in the United States & Canada.
What is a Stroke?
Stroke is a disease involving the blood vessels leading to or within the brain. The most common type of stroke occurs when one of these blood vessels is blocked, depriving a region of the brain of oxygen and nutrients. Depending on what part of the brain is affected, a stroke can cause sudden weakness in an arm or leg, difficulty speaking, or other symptoms.

Keeping Stroke Patients Healthy
Despite current treatments, 1 out of every 4 stroke patients will have another stroke or a heart attack within four years. Preventing this is a major goal in the care of stroke patients.

The Purpose of the IRIS Trial
The IRIS trial will test a new approach to preventing stroke or heart attack in patients who’ve had a stroke. The approach involves taking a medication called pioglitazone to reduce insulin resistance.

People with insulin resistance do not respond normally to insulin, a hormone that regulates blood sugar. This may lead to high blood sugar or diabetes. Over time, insulin resistance may also lead to atherosclerosis, the blood vessel disease that causes most strokes. About 1 in 2 patients with stroke has insulin resistance.
Who is Eligible for IRIS?

- Age 45 or older
- Not diabetic
- Recent stroke (within past 6 months)
- Not severely disabled from the recent stroke
- Insulin resistant (by blood test)

Certain conditions, like pregnancy, liver disease, atrial fibrillation, and heart failure may prevent participation.

Enrolling in IRIS

IRIS will enroll more than 3000 patients from over 60 health centers in the U.S. and Canada.

Details about the study will be reviewed with each patient. After all questions are answered, the patient will be asked to sign a consent form. The patient will then have a fasting blood test for insulin resistance. Only patients with insulin resistance will continue in the study.

What Happens During IRIS?

Eligible patients will be randomly assigned to two groups. Half of the participants will take the active medication, pioglitazone, and the other half will take a placebo (inactive look-alike pill). Neither the participant nor the doctors will know which pill is being taken until the end of the study.
What Happens, continued

Participants will stay on their study pill for an average of 4 years and will be followed closely for any new strokes or heart attacks. By comparing what happens to participants on pioglitazone or placebo, we will know if taking pioglitazone is effective in reducing the risk of future stroke or heart attacks.

■ Baseline Visit
At this visit with the study nurse, participants will be asked about their health and have an examination. The study medication will be started at one pill a day.

■ Telephone Calls
A study nurse will call every 2 weeks for the first 3 months. The nurse will administer a short health-related interview and answer any questions. The dose of the study medication will be slowly increased during this period. After the first 3 months, the nurse will call the participant every 4 months.

■ Follow-Up Visits
After 4 months, a blood test will be repeated. Once a year, a study nurse will meet with each participant for a brief interview, examination, and another blood test.
More on Pioglitazone

Pioglitazone or “pio” is a medication used to treat diabetics. It works by reducing insulin resistance. When diabetics take pioglitazone, insulin resistance is reduced and blood sugar improves. Pio never causes the blood sugar to fall below normal – unless a patient is also taking insulin or other diabetic medications.

Pioglitazone comes as a small white pill. It can be taken with or without food, and with or without other medications. Possible side effects may include mild leg swelling (edema) and weight gain (average 2-3 lbs.) Very rarely, pioglitazone may cause or worsen symptoms of heart failure.

More on Treating Insulin Resistance

Right now, medications like pio are not used to treat insulin resistance unless a patient is already diabetic. We don’t yet know if reducing insulin resistance in non-diabetics is of benefit. Several studies like ours are looking at this very important question.

Insulin resistance can also be reduced by lifestyle changes, such as following a good diet and getting exercise. In overweight patients, losing weight will help a lot. The study team and the IRIS website can provide more information on how to reduce insulin resistance.
More on Stroke Prevention

To prevent another stroke, patients should work closely with their doctors.

Prevention usually includes:
- taking aspirin or other blood thinner
- controlling high blood pressure
- treating high cholesterol
- stopping smoking
- eating properly

Personal doctors are always the best source of individualized advice. All patients who take part in IRIS will have their stroke risk factors monitored. Results will be sent to the participant and his or her doctors.

Your IRIS Study Site

Your IRIS Study Team

Principal Investigator

Study Coordinator

Telephone

www.iristrial.org