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News

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****Diabetes patients needed for study.**

DALLAS--Wanted: A group of very special volunteers for medical research.

The University of Texas Health Science Center at Dallas is seeking patients with insulin-dependent diabetes to participate in a major North American study of 250 volunteers in 21 medical centers. The study, Diabetes Control and Complications Trial, is sponsored by the National Institute of Arthritis, Diabetes and Digestive and Kidney Disease.

"The results of the study may change the way physicians around the world treat people with insulin-dependent diabetes," says Dr. Philip Raskin, associate professor of Internal Medicine and director of the UTHSCD portion of the study.

While the discovery of insulin in 1921 extended the life span and improved the quality of life for persons with diabetes, new ways to treat patients have been developed in the past 10 years. However, says the diabetes specialist, it is not known whether these newer methods--such as the insulin pump and more frequent injections than standard treatment prescribes--are better in preventing the complications of the disease. Raskin himself has been working with a large number of patients with insulin pumps for four years.

The study, which will last a minimum of two years, will try to answer two of the most complex questions facing diabetes researchers today. First, if blood sugar levels of people with insulin-dependent diabetes are kept as close as possible to the non-diabetic levels, will more, fewer or the same complications develop? Secondly, is it practical and safe to maintain normal blood glucose levels over long periods of time in patients with insulin-dependent diabetes?

Answering these questions is of paramount importance. While many persons who have diabetes have no or slight complications, many patients suffer from severe, often life-threatening problems caused by the disease. Complications may include the following:

- * Impairment of vision. At least 40 percent of diabetic patients show at least mild signs of diabetic retinopathy, a condition of damage to the retina, the light-sensitive tissue that lines the inside of the eye. As many as three percent may have severe loss of vision.

- * Damage to the small blood vessels of the kidney. This kind of damage may lead to kidney failure.

- * Damage to the body's nerve tissue. This major complication can lead to loss of feeling in the hands and feet. Without being able to rely on the sense of touch in these important areas of the body, the affected patient may be at risk from infections following ordinary household and yard injuries.

- * Damage to the large blood vessels. The most serious damage can occur in the vessels that supply blood to the heart, brain and legs. This kind of damage puts the patient at increased risk of heart attack, stroke and circulation problems.

(OVER)

At the present, says Raskin, there is no way to predict who will or will not develop complications or how severe the complications will be.

"Focus for the past 50 years in diabetes research has been on the relationship between blood glucose levels and complications from the disease," says Raskin. Some researchers believe that keeping blood glucose levels as near to non-diabetic levels as possible will prevent or delay the complications or make these complications less severe if they do occur. However, others believe that attempts to keep blood glucose levels near non-diabetic levels are not of proven benefit, are not practical, and may even be harmful.

"Before now there has been no way to do the study needed to understand the relationship between the blood-glucose and these complications. But in the past few years new, easier and more direct ways of measuring blood glucose levels and giving insulin have been developed. These new methods, such as the insulin pump, attempt to keep the blood glucose levels close to non-diabetic levels. With these new methods, we are now able to try to compare standard treatment of insulin-dependent diabetes with newer forms of treatment in order to find out whether the complications of diabetes can be prevented or their progression slowed," says the researcher.

All patients participating in the DCCT will receive treatment for their disease, says Raskin. Some will receive standard treatment (the most common treatment currently being offered by physicians to their patients), and some will receive one of the experimental programs. (Note: although this group is labeled "experimental," many physicians in private practice are currently using both the insulin pump and the multiple-injection treatment.) All diabetes-related care during the time the volunteer is in the study will be furnished to him or her at no cost. Patients will be assigned on a random basis to either one of the treatment groups. (This means that neither the volunteer nor the research physician can select the treatment group the patient is assigned to.) All risks to the voluntary study will be explained in detail to volunteers, and participants may withdraw at any time without penalty. If the two-year study is successful, researchers hope to expand the program to a 10-year look at questions being investigated.

Volunteers assigned to the standard group will give themselves one or two injections of insulin a day. The research physician will prescribe the type and dosage. A dietitian will work with the volunteer to develop a balanced diet to help control the disease, and the volunteer must do home urine tests on a regular basis. Self-administered blood glucose monitoring will be required only if the patient's status cannot be adequately measured by urine tests and/or other routine clinical assessments. In addition, a course in patient education will cover exercise, foot care, prevention and treatment of hypoglycemia and tips for management of "sick days."

Volunteers in the experimental group will receive insulin pumps or be put on a program involving three or four injections of insulin a day. These volunteers must spend five to 10 days in the hospital at the beginning of the study so the doctor can teach the volunteer how to manage the new treatment and make sure it is working safely. (This required hospitalization will be paid for by the program.) A dietitian will also work with the volunteers in the experimental program to work out a meal plan and to adjust it for the new methods of treatment. Blood glucose levels must be measured by the volunteer several times a day, as well as once a week at 3 a.m., to check for hypoglycemia (low blood sugar). These volunteers will also receive an educational program. In addition, the patient in the experimental program must see the doctor or another member of the research staff once a month for a routine checkup.

In order to enter the DCCT, a person must:

- * Be between the ages of 13 and 39. (Minors must have parent or parents' permission.)
- * Have had insulin-dependent diabetes for at least one year but no more than 15 years.
- * Have no severe complications.
- * Be free of other medical or psychological problems that would make it difficult or unsafe to participate in the study, such as high blood pressure, heart disease, kidney disease or chronic depression. (Volunteers will receive a series of tests to be sure these problems are not present.)
- * Be planning not to become pregnant for at least two years.
- * Be willing to carry out required responsibilities, such as record-keeping and home testing of blood or urine.
- * Live close enough to one of the DCCT medical centers so appointments at the medical center can be easily kept.
- * Be fairly sure he or she will not be moving away from the area in the near future.

For further information about the UTHSCD study call Sue Strowig at 214/688-3497.

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