

## Background

C-reactive protein (CRP) is a biomarker (blood chemical that can be measured), which shows the level of inflammation in the body. CRP goes up even at low levels of inflammation that can only be found by testing your blood. Studies show that if you have high levels of CRP, you may be at risk for heart and blood vessel diseases. These include heart attack, stroke, chest pain, leg pain, and other problems caused by “hardening or blockage of the arteries.” This is also known as atherosclerosis.

People with diabetes have a higher risk of atherosclerosis than people without diabetes. People with diabetes also tend to have high levels of CRP.

## What is the LANCET Trial?

The LANCET Trial will study diabetic patients who need to go on additional treatment for their diabetes and who also have high levels of CRP in their blood. We want to know whether starting insulin injections sooner is better than starting a pill to lower blood sugar and lower CRP. The insulin we will use in this study is called Lantus, and the pill is called metformin.

## Who is eligible to participate?

### Patients Must:

- Be between 18 and 79 years of age
- Have type 2 diabetes and currently taking no medications for diabetes or only one type of diabetes pill *other than metformin*
- Have high blood sugar and CRP levels
- Be willing to check your blood sugars daily – we will show you how to do this
- Be willing and able to take insulin injections *or* another pill for your diabetes
- Be willing to take a pregnancy test if you are a woman who could get pregnant

## Who is not eligible to participate?

### Patients Must Not:

- Have type 1 diabetes
- Currently use insulin or metformin
- Have heart failure in the past
- Have fasting blood sugar levels that are too high for the study ( $\geq 250$  mg/dl)
- Be pregnant, nursing, or want to get pregnant during the period of treatment
- Have liver or kidney disease
- Have recently started or changed doses of medications that could affect CRP levels – we will tell you what these are
- Be taking steroids or other anti-inflammatory medications for conditions such as lupus or rheumatoid arthritis
- Have had recent surgery or major injury within the past month