

Oral Insulin for Prevention of T1DM in Family Members at Risk

(HIC# 0710003160)

We are trying to find a way to delay or prevent type 1 diabetes. In this study, we are testing oral insulin (capsules of insulin crystals). We will see if treatment with oral insulin will result in fewer people developing diabetes compared to the people in the study who do not receive oral insulin. Participants in this study were screened in the Natural History Study. If the screening blood tests showed that you are at higher risk you may be invited to join this study. The oral insulin does not act in the body the same way that injected insulin does. There is some evidence that if a person eats the same protein (insulin) that the immune system is reacting to, the immune system will stop its attack. If you join this study, you are agreeing to take one study capsule a day and come in for study visits, which include blood tests. Half the people in this study will get capsules with insulin crystals and half will get placebo (sugar pills). This is a double-masked study

You can be screened for this study if:

- You are 3-45 years old
- The tests you took in the Natural History study showed that you are at moderate risk for developing type 1 diabetes

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