



Agenzia Italiana del Farmaco- AIFA
Via del Tritone, 181
00187 Rome
Italy

11 October 2018

Clinical Trial Study: Oral Insulin for Prevention of Diabetes in Relatives at Risk for Type 1 Diabetes Mellitus

EudraCT Number: 2006-006550-96

Protocol Number: 808040005

Sponsor: TrialNet Study Group

Dear Sir or Madam,

The San Raffaele Hospital Ethics Committee approved the TrialNet study "Oral Insulin for the Prevention of Diabetes in Relatives at Risk for Type 1 Diabetes Mellitus" on 01 March 2007. Study enrollment commenced on 02 March 2010.

The San Raffaele Hospital was the only active site in Italy.

13 participants were enrolled and randomized into the study at the San Raffaele Hospital; 1 participant transferred from outside Italy making 14 participants. The participants were from both the adult and pediatric populations.

This study was completed globally on 1 November 2017. In Italy, the last active study visit was performed in May 2017. The San Raffaele Hospital Ethics Committee received notification and a close of study report in January 2018.

We are at your disposal for any additional information you may need.

Kind regards

A handwritten signature in black ink, appearing to read "E. Bosi".

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