

GI Dynamics bags approval for I-STEP clinical study of diabetes & obesity in India

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Trial to focus on reduction of haemoglobin A1c for patients diagnosed with type 2 diabetes and obesity



GI Dynamics, a US-based medical device company that is developing the EndoBarrier System for patients diagnosed with type 2 diabetes and obesity, has received regulatory approval to begin enrollment in the I-STEP clinical trial in India.

I-STEP is a multi-centre, randomised, pivotal study evaluating the safety and efficacy of EndoBarrier for glycemic improvement in patients with inadequately controlled type 2 diabetes and obesity and will be conducted exclusively in partnership with the Apollo Hospital System and Apollo Sugar Clinics.

This study, which is intended to follow 100 subjects up to 24 months, will evaluate EndoBarrier in patients who fall within a predetermined haemoglobin A1c range.

In addition to partnership in the I-STEP clinical trial, GI Dynamics and Apollo Sugar have agreed to work toward setting the terms of a joint-partnership that will focus on the marketing, distribution, and clinical support of EndoBarrier® to appropriate patients throughout India and Southeast Asia.