

**NCT02394275**

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**Study Title: A Prospective, Trial of Frozen-and-Thawed Fecal Microbiota Transplantation for Recurrent *Clostridium difficile* infection.**

**Sample size and the justification for the assumptions:**

180 participants were recruited based on the sample size and efficacy result of the trial comparing frozen versus fresh fecal microbiota transplantation trial. The control (Frozen) FMT efficacy was 85%.

Based on a one-sided hypothesis test, the sample size will be 180 accounting for 10% attrition with 5% significance and 80% power.

**Type of statistical analyses**

The clinical response rate will be determined using standard binary outcome protocols. The primary endpoints of clinical response, recurrence of CDI and treatment failure will be determined.