

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.