Amendments made to the FLORA trial protocol version 1.0

Amendment 01, Oct 2016
I. Advertisement in magazines published by patient organizations to enhance trial recruitment.
   II. Nation-wide recruitment.
   III. Using thawed frozen FMT products instead of same-day stool donations.

Amendment 02, Dec 2016
I. Adding two weekly questionnaires: HAQ-DI and DLQI.
   II. Collection of blood biobank samples at 1 month and 3 months.
   III. No donor compensation in relation to stool deliveries.

Amendment 03, Dec 2016
I. Collection of swabs from skin and mouth at baseline, 1 month, 3 months and 6 months.
   II. Testing for coeliac disease in the stool donor screening programme.
   III. Collection of biobank blood samples with the purpose of performing immunological analysis matching those performed on biobank blood samples collected from trial patients.

Amendment 04, May 2017
I. Quality assurance project evaluating the clinical outcome in twelve patients with CDI after receiving FMT using FLORA stool donations.

Amendment 05, Aug 2017
I. Two additional questionnaires regarding diet and weekly exercise (patients and donors).

Amendment 06, Aug 2017
I. Collection of biobank faecal samples 3- and 6 months after the last stool donation (donors).

Amendment 07, Nov 2018
I. Inclusion of patients treated with orally administered MTX.

Amendment 08, Feb 2019
I. Extension of the quality assurance project in patients with CDI to explore decline in treatment effect when using FLORA stool donations stored for more than one year.

Amendment 09, Oct 2019
I. The upper age limit was changed from 70 to 75 years.