Decrease of faecal calprotectin in adults after initiation of Orkambi®, a Registry-based study

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Objectives: Orkambi® is since 1st July 2018 available for restricted prescription in Sweden. Follow-up after 1, 3, 6, 9 and 12 months is mandatory and data is entered in the National CF Registry. F-calprotectin, a marker of intestinal inflammation and reported elevated in many CF patients, was recommended for analysis at start and after 3 and 12 months.

Methods: All adults (>18 years) with f-Calprotectin obtained at start of Orkambi® and at a follow-up visit ≥3 months later were included. If > 1 follow-up value was available then the latest result was used. The CFQR GI symptom score and the CFQUEST GI score were included in the analysis.

Results: Forty-four adults (25 males) with a mean age of 31.9 (SD 10.1) years were included. The median f-Calprotectin decreased from 93.5 (8–6000) at start to 48.5 (5–249) ($p < 0.001$, Wilcoxon signed rank test) after a median follow-up time of 4 (3–15) months. The mean CFQR GI symptom score at start and follow-up did not change and was 78.1 (SD 17.5) and 79.0 (SD18.7) respectively. The CF-QUEST GI scorewas also unchanged and 83.9 (15.7) and 85.4 (SD 16) respectively. The Spearman correlation between f-Calprotectin and CFQR GI symptoms was weak at start ($N = 39$, $r = 0.109$, $p = 0.51$) and follow-up ($N = 41$, $r = 0.111$, $p = 0.49$) and also between f-Calprotectin and CF-QUEST GI at start ($N = 35$, $r = 0.04$, $p = 0.82$) and followup ($N = 30$, $r = 0.01$, $p = 0.95$). Thirteen (30%) patients had increased f-Calprotectin (>150 mg/kg) at start and 3 (7%) at follow-up.

Conclusion: The inflammation expressed in the GI tract seems to decrease after Orkambi®, while not accompanied by a change in GI symptom scores. Repeated sampling over time in a larger cohort is needed to draw conclusions.