

New Specialized Kombucha-Based Non-alcoholic Pasteurized Beverage Shows Favorable Profile of Short-Term Safety and Tolerability in Patients With Constipation.

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Objectives: Kombucha is a globally known beverage, perceived as “healthy”. It may be a basis for the development of new specialized beverages to increase dietary fiber consumption. However, safety and tolerability of the kombucha-based beverages is poorly studied yet. Aim: to assess short-term safety and tolerability of new kombucha-based pasteurized specialized non-alcoholic beverage, enriched with inulin.

Methods: This study (NCT05164861) enrolled subjects with constipation-predominant irritable bowel syndrome (per ROME IV). The subjects were randomized to receive either 220 ml of the non-alcoholic kombucha-based pasteurized beverage (KG), enriched with inulin (1.15 g/100ml) or 220 ml water (control group, CG), for 10 days. Except study product, subjects were advised to follow their usual diet. Organoleptic evaluation of the beverage; assessment of symptoms

(abdominal pain/discomfort, abdominal fullness, bloating, heartburn) with the use of 5-point Likert scale; blood chemistry and hematology were performed before (BL) and on the 10th day of study (EOT). Patients were asked to report any adverse events during the study period.

Results: There were 20 subjects in KG and 20 in CG groups. New specialized food product was well-tolerated, no SAE occurred during the study. No exacerbation of the pre-existing symptoms was observed in KG, including abdominal pain/discomfort (1.28 ± 0.56 vs 1.25 ± 0.56 ; $p > 0.05$), abdominal fullness (1.53 ± 0.69 vs 1.22 ± 0.47 ; $p > 0.05$), bloating (1.60 ± 0.64 vs 1.37 ± 0.60 ; $p > 0.05$), and heartburn (1.28 ± 0.62 vs 1.25 ± 0.52 ; $p > 0.05$) during the study. The rate of AEs was low (5%) and did not differ compared to CG. Mean integrative score of organoleptic evaluation of the beverage was good ($91.0 \pm 13.7\%$) with non-significant increase at EOT ($94.2 \pm 6.5\%$). No laboratory AE were observed.

Conclusions: This study suggest that new specialized kombucha-based drink enriched with inulin is well-tolerated, and has favorable safety profile.

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