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Article in Press

Small Amounts of Gluten in Subjects With Suspected Nonceliac Gluten Sensitivity: A Randomized, Double-Blind, Placebo-Controlled, Cross-Over Trial

Antonio Di Sabatino, Umberto Volta, Chiara Salvatore, Paolo Biancheri, Giacomo Caio, Roberto De Giorgio, Michele Di Stefano, Gino R. Corazza

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Abstract | Full Text | Images | References | Supplemental Materials

Background & Aims

There is debate over the existence of nonceliac gluten sensitivity (NCGS) intestinal and extraintestinal symptoms in response to ingestion of gluten-containing foods by people without celiac disease or wheat allergy. We performed a randomized, double-blind, placebo-controlled, cross-over trial to determine the effects of administration of low doses of gluten to subjects with suspected NCGS.

Methods

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We enrolled 61 adults without celiac disease or a wheat allergy who believed ingestion of gluten-containing food to be the cause of their intestinal and extraintestinal symptoms. Participants were assigned randomly to groups given either 4.375 g/day gluten or rice starch (placebo) for 1 week, each via gastrosoluble capsules. After a 1-week gluten-free diet, participants crossed over to the other group. The primary outcome was the change in overall (intestinal and extraintestinal) symptoms, determined by established scoring systems, between gluten and placebo intake. A secondary outcome was the change in individual symptom scores between gluten vs placebo.

Results

According to the per-protocol analysis of data from the 59 patients who completed the trial, intake of gluten significantly increased overall symptoms compared with placebo (P = .034). Abdominal bloating (P = .040) and pain (P = .047), among the intestinal symptoms, and foggy mind (P = .019), depression (P = .020), and aphthous stomatitis (P = .025), among the extraintestinal symptoms, were significantly more severe when subjects received gluten than placebo.

Conclusions

In a cross-over trial of subjects with suspected NCGS, the severity of overall symptoms increased significantly during 1 week of intake of small amounts of gluten, compared with placebo. Clinical trial no: ISRCTN72857280.

Keywords:
Extraintestinal, Gluten, Intestinal, Nonceliac Gluten Sensitivity, Placebo

Abbreviations used in this paper:
AGA (antigliadin antibodies), ANOVA (analysis of variance), GFD (gluten-free diet), NCGS (nonceliac gluten sensitivity), W (week)

Conflicts of interest The authors disclose no conflicts.

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