



Abstract Food Allergen-Specific Substitutive Diet as a Proposed Tool for Adverse Reactions to Foodstuffs Management: The ALASKA Study[†]

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- ⁺ Presented at the 14th European Nutrition Conference FENS 2023, Belgrade, Serbia, 14–17 November 2023.

Abstract: The prevalence of adverse reactions to foodstuffs (ARFS), such as food allergy (FA) and food intolerance (FI), has been increasing worldwide during the past decades. Currently, strict food allergen avoidance is the principal recommended treatment of ARFS. However, individuals with ARFS following elimination diets have shown crucial micronutrient deficiencies. There is an emerging necessity for an effective ARFS strategy which may help mitigate the nutritional deficiency problem. To develop a strategy for the management of ARFS including a food allergen-specific substitutive diet (FASSD) together with the evaluation of the clinical picture, food consumption, food-allergen profile and quality of life (QoL) in adults with ARFS. The interest of this study is focused on current growing public health problems: FA and FI. The following measurements will be considered: (1) informed consent and inclusion/exclusion criteria forms; (2) symptomatology, food consumption and dietary intake: PSIMP-ARFSQ-10 and FBFC-ARFSQ-18 validated ARFS-specific questionnaires and a 24 h dietary recall interview; (3) immunology: food-allergen profile (IgE and IgG₄ antibodies against 82 common Mediterranean food and beverages) using HELIA® Helmed line immunoassay analyzer (Aesku.Diagnostics, Wendelsheim, Germany); (4) enzymatic activity: lactose and fructose breath test using Cerascreen[®] hydrogen and methane detector kit (Cerascreen GmbH, Schwerin, Germany); (5) QoL aspects: SF-12 and FAQLQ-AF validated questionnaires; (6) six-month FASSD intervention; (7) repetition of measurements from 1 to 6; (8) adjustment of the FASSD. The six-month FASSD was designed for adults aged 18 to 70 years according to individual immunological and enzymatic results. Substitutive foodstuffs were chosen using BEDCA, USDA and NCCDB food composition databases reference tables when they represented the same nutritional value as the foodstuff with positive IgE and IgG₄ reaction (\geq 3.5 kU_A/L). Particular attention was paid to vitamin A, D, E, C, folate, B1, B2, B3, B6, B12, calcium, iron, potassium, magnesium, sodium, phosphorus, iodine, selenium and zinc when choosing the substitutive foodstuffs. The FASSD was developed as a proposed tool to improve health and QoL of adults with symptoms associated with ARFS.

Keywords: allergens; diet; food hypersensitivity; nutrition therapy



Citation: Pantoja-Arévalo, L.; Gesteiro, E.; López-Seoane, J.; Nehari, A.; Matthias, T.; Urrialde, R.; González-Gross, M. Food Allergen-Specific Substitutive Diet as a Proposed Tool for Adverse Reactions to Foodstuffs Management: The ALASKA Study. *Proceedings* 2023, *91*, 313. https://doi.org/10.3390/ proceedings2023091313

Academic Editors: Sladjana Sobajic and Philip Calder

Published: 9 February 2024



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Funding: This research was funded, in part, by the ImFINE Research group's own funds. Additional funding was from the Instituto de Salud Carlos III through CIBEROBN (CB12/03/30038), which is co-funded by the European Regional Development Fund. Lisset Pantoja-Arévalo is supported by the Universidad Politécnica de Madrid by means of a predoctoral contract (project number: P2011600273).

Institutional Review Board Statement: The study was conducted in accordance with the Declaration of Helsinki, approved by the Ethics Committee of the Universidad Politécnica de Madrid (reference number 20200602) and registered on ClinicalTrials.gov (NCT05802017).

Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

Data Availability Statement: The ALASKA study is ongoing now. The enrollment of participants has been started since April 2022. It is ongoing now and datasets have not been closed.

Conflicts of Interest: T.M. is part of the Aesku.Diagnostics GmbH staff. T.M. did not participate in the design of the protocol or in the analysis and interpretation of the data outcomes. The rest of the authors have nothing to report.

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