

The effect of dietary fat content on the recurrence of pancreatitis – Pre-study protocol of the EFFORT-randomized controlled trial

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Introduction

Patients experiencing an episode of acute pancreatitis (AP) are often advised to maintain a low-fat diet in order to avoid complications, recurrent episodes (ARP) and progression to chronic pancreatitis (CP). While in some instances other means exist to help avoid recurrence – such as cholecystectomy in biliary AP, and drinking cessation in alcoholic AP – a dietary intervention could be the only option in idiopathic cases. However, presently **there is no evidence to support this recommendation and it is not included in any of the AP guidelines**. Our aim was to conduct a randomized controlled trial (RCT) to determine the possible benefits of dietary fat reduction in AP patients.

Design and interventions

This study will be a **prospective, multicenter RCT**. 384 eligible patients will be randomly assigned in a 1:1 ratio to one of two dietary interventions: (1) a 'reduced fat diet' with **15% fat**, 65% carbohydrates, 20% proteins; (2) a 'standard healthy diet' (based on WHO recommendations) with **30% fat**, 50% carbohydrates and 20% proteins (Figure 1). Baseline values for appropriate outcomes will be collected, a centrally trained dietician will assess dietary habits by a food frequency questionnaire (FFQ) then provide recommendations according to the group of the participant. Dietary guidance will be repeated at month 12. Initially a 3rd ketogenic diet arm was planned but proved unfeasible.

Authors declare no conflicts of interest

Inclusion and exclusion criteria

Inclusion criteria: (1) Individuals with **at least 2 episodes of AP in the last 2 years** preceding the inclusion with (2) the **last episode being idiopathic**, who are (3) ≥ 18 years old.

Exclusion criteria: Individuals (1) already receiving regular nutritional guidance (with medical indication), (2) in critical condition or in terminal stage of cancer (with an expected survival < 2 years), (3) undergoing treatment for active malignancy, (4) uncontrolled diabetes mellitus, (5) pregnant/nursing, (6) with a BMI < 18.5 , (7) regularly receiving systemic corticosteroids, (8) consuming more alcohol than: 5 units per day or 15 units per week for men; 4 units per day or 8 units per week for women.

Outcomes

Primary: **ARP and/or all-cause mortality (composite)**

Secondary: Pancreas specific and cardiovascular mortality, body mass index (BMI), serum lipid parameters including: total cholesterol, triglycerides (TG), HDL-cholesterol and LDL-cholesterol; systolic and diastolic blood pressure (SBP, DBP); adherence to dietary recommendations (based on FFQ), adverse events.

Importance

The results of our study will determine the effect of modifying dietary fat content on recurrence and mortality in idiopathic ARP cases i.e. the patient group in which there is a dire need for interventions to positively influence the course and progression of the disease.

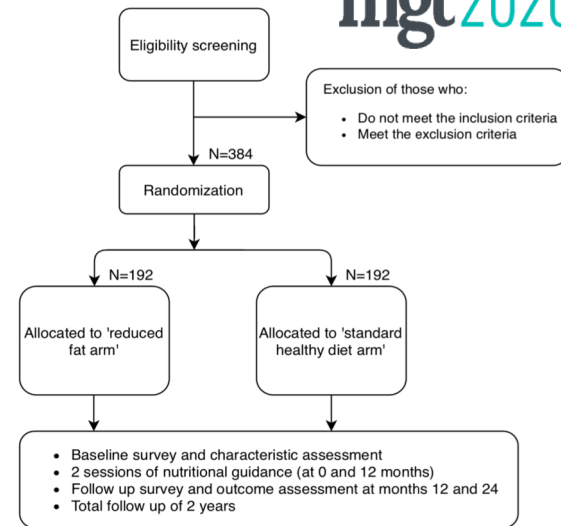


Figure 1 – Flow diagram summarizing study design

Centers are welcome to join!
Planned start: December 2020
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