Recurrent acute pancreatitis prevention by the elimination of alcohol and cigarette smoking (REAPPEAR): protocol of a randmozied controlled trial and a cohort study

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Objectives

The study encompasses a randomized controlled trial (**REAPPEAR-T**) and a concomitant cohort study (**REAPPEAR-C**). The REAPPEAR-T's objective is to investigate the effect of an **alcohol and smoking cessation program** combined with **patient education** on the recurrence rate of alcohol-induced acute pancreatitis (AP). Additionally, the REAPPEAR-C's objective is to investigate the **effect of alcohol and smoking cessation** (irrespective of intervention) **on the recurrence rate** of alcohol-induced AP.

Eligibility

Patients hospitalized with **alcohol induced AP aged 18-65, currently smoking** (for at least 1 years), with **less than 3 documented AP episodes** altogether, who received a **standard intervention** on the disease itself and the importance of alcohol and smoking are eligible. Other etiologies need to be ruled out. Patients taking part in cessation programs will not be enrolled.

Flow and timing

The enrollment period lasts from 48 hours before until one week after hospital discharge. Participants will be assigned to the **cessation program or the control group** (see Figure 1). Patients in the **cessation program** will attend **3-monthly visits** while the **controls** will only have **yearly visits.** Estimated **sample size** is **182 patients per arm**.

Assessment and biobank

The **Alcohol Use Disorders Identification Test**, the **Fagertsrom Test for Nicotine Dependence**, the **Drinking Motives Questionnaire**, and the **EQ-5D-5L** questionnaire will be used. **Data on hospitalisations** and **healthcare costs** will be obtained. All visits contain body weight and blood preassure measuremetns and routine laboratory tests.
Blood, hair and urine samples will be collected for later **biomarker measurements.**

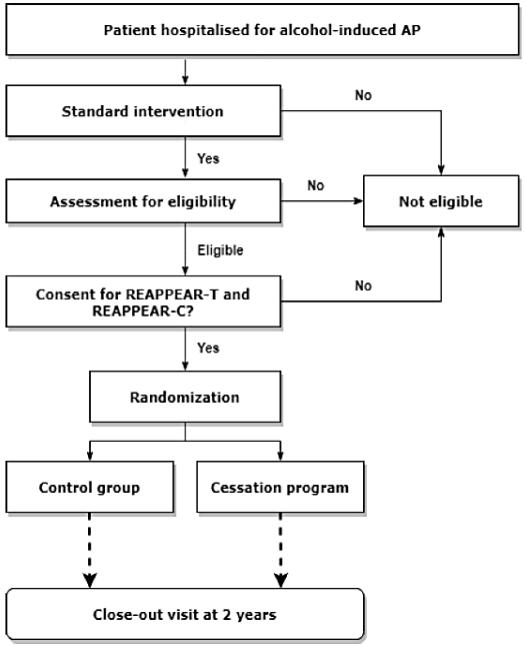

Figure 1. Study flowchart

Cessation program (intervention group)

Patients in the cessation program will receive a structured **intervention** at **every visit**, based on **psychoeducational and motivational interviewing techniques**, lasting approximately **30 minutes,** provided by a **specially trained study nurse.** Topics include the **importance of alcohol and smoking cessation** an **direct feed-back** on GGT and MCV values will be given. Interventions will be **individualized** according to the motivation assessed previously.

Endpoints

The **primary endpoint** will be the **recurrence** of AP irrespective of etiology (**rate of event**) **and/or mortality** within **2 years**.
Secondary endpoints include alcoholic recurrance, length of hospitalisation, changes of alcohol consumption and smoking, chronic pancreatitis and healthcare costs.

Timeline

November 2020: protocol publication, registration
December 2020: Start of enrollment

Ethical approval: 40394-3/2020EÜIG

OPEN FOR PARTICIPATION!
Contact ocskay.klementina@gmail.com