

# The role of exercise in metabolism and quality of life after pancreatectomy

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|----------------------------------------|---------------------------------------------------|---------------------------------------------------------------------------------------------------|
| <b>Submission date</b><br>03/11/2015   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol            |
| <b>Registration date</b><br>16/11/2015 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>10/06/2019       | <b>Condition category</b><br>Cancer               | <input type="checkbox"/> Individual participant data                                              |

## Plain English summary of protocol

### Background and study aims

There are no studies that provide sufficient information on how exercise can influence the quality of patient's life after resection (removal) of the pancreas due to pancreatic disease, such as cancer. The aim of this study is to find out whether exercise can help in controlling blood glucose levels and oxidative stress after pancreatectomy (surgery to remove the pancreas).

### Who can participate?

Adult patients with pancreatic cancer that are fit for surgery.

### What does the study involve?

The participants are randomly allocated into one of two groups. All participants have a pancreatectomy. The participants in the exercise group exercise using a static bicycle for 12 weeks. The participants in the control group do not exercise. Blood glucose, HBA1c (glycated haemoglobin, which is a form of haemoglobin that is measured to identify average plasma glucose concentrations in the blood), albumin and the uric acid levels for all participants in both groups are measured every 4 weeks for the duration of the study.

### What are the possible benefits and risks of participating?

There are no risks for the participants.

### Where is the study run from?

Agios Dimitrios General Hospital (under the control of Aristotle University Thessaloniki)

### When is study starting and how long is it expected to run for?

May 2014 to June 2016

### Who is funding the study?

Agios Dimitrios General Hospital (Greece)

### Who is the main contact?

Dr Anastasios Katsourakis  
tasoskatsourakis@hotmail.com

# Contact information

## Type(s)

Scientific

## Contact name

Dr Anastasios Katsourakis

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# Additional identifiers

## Protocol serial number

02/pancreas/05.2014

# Study information

## Scientific Title

The influence of exercise on blood glucose control and the anti-oxidative ability of the blood in patients after pancreatectomy: a randomized controlled trial

## Acronym

EQAP (Exercise and Quality of life After Pancreatectomy)

## Study objectives

The aim of this study is to investigate whether pancreatectomy helps to control blood glucose after exercise, improves the anti-oxidative ability of the blood in patients and improves patient quality of life.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Bioethics committee and Deontology, Medical School of Aristotle University Thessaloniki, 29/10 /2015, ref: 166/ 29.10.2015

## Primary study design

Interventional

## Study design

Interventional single-centre, randomized controlled trial

**Study type(s)**

Quality of life

**Health condition(s) or problem(s) studied**

Pancreatic disease, mainly neoplastic tumors of the pancreas

**Interventions**

Participants are randomly allocated to one of two groups, the intervention group and the control group.

Both groups will undergo a pancreatectomy. The surgical procedure will be open and according to the location of the tumor the patient will undergo a Longmire Traverso/Whipple operation (pancreatoduodenectomy) or distal pancreatectomy with or without preservation of the spleen. Four weeks after the operation the participants in the intervention group will start to exercise, which involves 30 minutes on a static bicycle (60% of maximum heart rate) for 12 weeks. The participants in the control group do not start to exercise.

**Intervention Type**

Mixed

**Primary outcome(s)**

Measurement of blood glucose levels, HBA1c, albumin and uric acid, 12 weeks after the initiation of exercise (once every 4 weeks interval)

**Key secondary outcome(s)**

Evaluation of the quality of life (QoL) in both groups 12 weeks after the initiation of exercise

**Completion date**

30/06/2016

## **Eligibility**

**Key inclusion criteria**

Adult patients with pancreatic neoplasms that are fit for surgery

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**Total final enrolment**

43

**Key exclusion criteria**

1. Age >75 years old
2. ASA >2
3. Non resectable pancreatic tumor (according to the guidelines)
4. Pregnancy

**Date of first enrolment**

30/05/2014

**Date of final enrolment**

30/06/2016

**Locations****Countries of recruitment**

Greece

**Study participating centre**

**Agios Dimitrios General Hospital of Greece**

2 Eleni Zografou Street

Thessaloniki

Greece

GR-54634

**Sponsor information****Organisation**

Agios Dimitrios General Hospital scientific committee and Aristotle University Thessaloniki

**ROR**

<https://ror.org/02j61yw88>

**Funder(s)****Funder type**

Hospital/treatment centre

**Funder Name**

Agios Dimitrios General Hospital

# Results and Publications

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Tasos Katsourakis (tasoskatsourakis@hotmail.com). Type of data that will be shared: all data will be available. When the data will be available: starting 01/10/2017. For how long: no limit. What type of analyses: demographic and surgical details, repeated measures ANOVA for the results. Consent was obtained from all participants, no ethical or legal restrictions.

## IPD sharing plan summary

Available on request

## Study outputs

| Output type                     | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> | results | 01/01/2019   | 11/01/2019 | Yes            | No              |
| <a href="#">Results article</a> | results | 01/01/2020   | 10/06/2019 | Yes            | No              |