

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

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

ORCID ID

<http://orcid.org/0000-0002-5151-9449>

Contact details

2 Elenis Zografou str

Thessaloniki

Greece

GR- 54634

+30 2313 322 178

tasoskatsourakis@hotmail.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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)

Study design

Interventional single-centre, randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Quality of life

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

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 measure

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

Secondary outcome measures

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

Overall study start date

28/05/2014

Completion date

30/06/2016

Eligibility

Key inclusion criteria

Adult patients with pancreatic neoplasms that are fit for surgery

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

40 patients

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

Sponsor details

2 Elenis Zografou str
Thessaloniki
Greece
GR-54634
+30 2313 322 100/178
tasoskatsourakis@hotmail.com

Sponsor type

Hospital/treatment centre

ROR

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

Funder(s)**Funder type**

Hospital/treatment centre

Funder Name

Agios Dimitrios General Hospital

Results and Publications**Publication and dissemination plan**

The trialists intend to publish the results immediately after the recruitment of a statistically significant number of patients and about 2 weeks later after the statistical analysis.

Intention to publish date

01/11/2017

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?
Results article	results	01/01/2019	11/01/2019	Yes	No
Results article	results	01/01/2020	10/06/2019	Yes	No