

Prehabilitation for patients undergoing major abdominal surgery

Submission date 20/11/2014	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 04/12/2014	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 25/01/2019	Condition category Surgery	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

When people have surgery, it is common practice for them to undergo postoperative rehabilitation to help them recover from the procedure and improve clinical outcome. However, it is possible that prehabilitation, a training programme to improve physical fitness before the surgery takes place, may be of more benefit. We want to see how possible it is to run a study from a number of different hospitals that compares the effects of a comprehensive prehabilitation programme with standard care (postoperative rehabilitation). We will look at how a prehabilitation programme helps patients recover from major abdominal surgery and whether it results in a better health-related quality of life, better physical fitness level, less pain and a shorter stay in hospital than patients that receive standard care.

Who can participate?

Adults scheduled for major abdominal surgery.

What does the study involve?

Participants are randomly allocated to attend a prehabilitation programme before their surgery or a standard rehabilitation programme after surgery.

What are the possible benefits and risks of participating?

We believe that patients would benefit from the prehabilitation intervention. No risk for any patient involved in the study is expected.

Where is the study run from?

1. University Hospital "Lozano Blesa" (Hospital Clinico Universitario de Zaragoza) (Spain)
2. University Hospital de Elche (Hospital Univeritario de Elche) (Spain)
3. University Hospital Infanta Leonor (Hospital Infanta Leonor) (Spain)
4. University Hospital Fundación Jiménez Díaz (Fundacion Jimenez Diaz) (Spain)
5. Hospital de la Ribera (Spain)
6. Hospital La Mancha Centro (Spain)

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

March 2013 to July 2020

Who is funding the study?
Investigator initiated and funded (Spain)

Who is the main contact?
Professor Jose-M Ramirez

Contact information

Type(s)
Scientific

Contact name
Prof Jose-M Ramirez

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Department of Surgery
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Additional identifiers

Study information

Scientific Title
Prehabilitation for patients undergoing major abdominal surgery with an enhanced recovery surgical protocol compared to traditional rehabilitation

Study objectives
Prehabilitation (the process of enhancing an individual's functional capacity before scheduled surgery, aimed at improving the patient's tolerance to surgical stress) increases functional capacity compared to traditional postoperative rehabilitation. This preoperative improvement will lead to earlier recovery and less morbidity

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical committee of Clinical Research, 01/01/ 2014. ref: CP.-CI. P113/0167

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Patient scheduled for major abdominal surgery for benign or malignant conditions

Interventions

Prehabilitation program initiated before surgery against a rehabilitation program (traditional care) initiated after surgery.

Intervention Type

Procedure/Surgery

Primary outcome(s)

Functional capacity as measured by the 6 minutes walking test (6MWT)

Key secondary outcome(s)

1. Post-operative morbidity
2. Hospital Stay
3. Quality of life

Completion date

01/07/2020

Eligibility**Key inclusion criteria**

Patient scheduled for major abdominal surgery

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

Patient classified as ASA IV with severe systemic disease that is a constant threat to life

Date of first enrolment

01/06/2013

Date of final enrolment

01/07/2019

Locations

Countries of recruitment

Spain

Study participating centre

University Hospital "Lozano Blesa" (Hospital Clinico Universitario de Zaragoza)

Avda. San Juan Bosco

Zaragoza

Spain

15 50009

Study participating centre

University Hospital de Elche (Hospital Univeritario de Elche)

Spain

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Study participating centre

University Hospital Infanta Leonor (Hospital Infanta Leonor)

Spain

-

Study participating centre

University Hospital Fundación Jiménez Díaz (Fundacion Jimenez Diaz)

Spain

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Study participating centre

Hospital de la Ribera

Spain

-

Study participating centre

Hospital La Mancha Centro

Spain

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Sponsor information

Organisation

Department of Surgery, University Hospital of Zaragoza

Organisation

Biomedical Research Centre of Aragon (Grupo Español de Rehabilitación Multimodal (GERM))

Organisation

University of Zaragoza

ROR

<https://ror.org/012a91z28>

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded (Spain)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Stored in repository