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Prehabilitation for patients undergoing major abdominal surgery

Submission date
20/11/2014

Recruitment status
No longer recruiting

Registration date
04/12/2014

Overall study status
Completed

Last Edited
25/01/2019

Condition category
Surgery

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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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Contact details
Department of Surgery
University Hospital
Zaragoza
Spain
50009

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

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. PI13/0167

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

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

Overall study start date
01/03/2013

Completion date
01/07/2020

Eligibility

Key inclusion criteria
Patient scheduled for major abdominal surgery

Participant type(s)

Patient

Age group
Adult

Sex
Both

Target number of participants
100

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
-

Study participating centre
University Hospital Infanta Leonor (Hospital Infanta Leonor)
Spain
-

Study participating centre

University Hospital Fundación Jiménez Díaz (Fundacion Jimenez Diaz)
Spain
-

Study participating centre
Hospital de la Ribera
Spain
-

Study participating centre
Hospital La Mancha Centro
Spain
-

Sponsor information

Organisation
Department of Surgery, University Hospital of Zaragoza

Sponsor details
San Juan Bosco 15
Zaragoza
Spain
50009

Sponsor type
University/education

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

Sponsor details
Avda. San Juan Bosco 13
Zaragoza
Spain
50009

Sponsor type
Government

Website

www.iacs.aragon.es

Organisation
University of Zaragoza

Sponsor details

Sponsor type
Not defined

Website
http://www.unizar.es/

ROR
https://ror.org/012a91z28

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded (Spain)

Results and Publications

Publication and dissemination plan
To be confirmed at a later date.

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Stored in repository