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Abdominoplasty and incisional hernia repair

Submission date	Recruitment status	[_] Prospectively registered
28/01/2015	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
09/02/2015	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
18/02/2022	Digestive System	

Plain English summary of protocol

Background and study aims
Abdominoplasty (surgical removal of excess fat or skin) is one of the most popular cosmetic surgeries performed by surgeons throughout the world. The continuing advances in this area can help improve outcomes. The combination of abdominoplasty and hernia repair is expected to further improve outcomes, but may have a negative impact on outcomes. The aim in this study is to find out whether abdominoplasty at the time of hernia repair modifies the incidence of complications and recurrence.

Who can participate?
Women who are overweight and have hernia

What does the study involve?
Participants will be randomly allocated to hernia repair alone or abdominoplasty and hernia repair.

What are the possible benefits and risks of participating?
The possible benefits are less infection, better healing and improved patient satisfaction. A possible risk is a negative effect on the outcome measures.

Where is the study run from?
Morales Meseguer University Hospital (Spain)

When is the study starting and how long is it expected to run for?
From January 2012 to December 2014

Who is funding the study?
University of Medicine (Spain)

Who is the main contact?
Professor Alfredo Moreno-Egea
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Contact information

Type(s)
Scientific

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Study information

Scientific Title
Effect of abdominoplasty and incisional hernia repair on morbidity: a randomised controlled trial

Acronym
AP-IHR

Study objectives
Does the combination of abdominoplasty and hernia repair modify morbidity?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the University Morales Meseguer Hospital (Spain), 12/01/2012

Primary study design
Interventional

Study design
Single-centre randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Abdominoplasty with concurrent hernia repair

Interventions

1. Hernia repair
2. Abdominoplasty and hernia repair

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Surgical-site infection
2. Wound disruption
3. Seroma
4. Haematoma
5. Time of surgery
6. Hospital stay

These outcomes will be assessed at 1 month, 3 months, 6 months, 12 months and 24 months.

Key secondary outcome(s)
General complications (pulmonary embolism, pneumonia or sepsis); these will be assessed at 1 month, 3 months, 6 months, 12 months and 24 months.

Completion date
31/12/2014

Eligibility

Key inclusion criteria
1. Ventral hernia
2. Obesity
3. Age 40–85 years
4. American Society of Anesthesiologists Physical Status classification controlled

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
1. Age < 40 years
2. Strangulated hernia
3. Malignant diseases
4. Mental illness
5. Circumstances that might compromise the patient’s cooperation
6. Refusal to give informed consent

Date of first enrolment
01/01/2012

Date of final enrolment
30/12/2014

Locations

Countries of recruitment
Spain

Study participating centre
Morales Meseguer University Hospital
Murcia
Spain
30008

Sponsor information

Organisation
University of Medicine

ROR
https://ror.org/03p3aeb86

Funder(s)

Funder type
University/education

Funder Name
University of Medicine (Spain)

Results and Publications

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		28/04/2016	18/02/2022	Yes	No