

Abdominoplasty and incisional hernia repair

Submission date 28/01/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 09/02/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 18/02/2022	Condition category Digestive System	<input type="checkbox"/> Individual participant data

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

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

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

Study design

Single-centre randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet.

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 measure

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.

Secondary outcome measures

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

Overall study start date

01/01/2012

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

Age group

Adult

Sex

Female

Target number of participants

Hernia repair (n=20) and abdominoplasty and hernia repair (n=20)

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

Sponsor details

5 Avda Teniente Flomesta
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moreno-egea@ono.com

Sponsor type

Hospital/treatment centre

Website

www.universidaddemurcia.es

ROR

<https://ror.org/03p3aeb86>

Funder(s)

Funder type

University/education

Funder Name

University of Medicine (Spain)

Results and Publications

Publication and dissemination plan

June 2015

Intention to publish date

30/06/2015

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