# Abdominoplasty and incisional hernia repair

Submission date	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>		
28/01/2015		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 moreno-egea@ono.com

# Contact information

#### Type(s)

Scientific

#### Contact name

Mr Alfredo Moreno-Egea

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# Additional identifiers

#### Protocol serial number

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

### 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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes