

# Is inguinal hernia repair possible with glue?

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<b>Registration date</b> 29/01/2013	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 20/09/2016	<b>Condition category</b> Digestive System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

An inguinal hernia occurs when fatty tissue or a part of the bowel pokes through a weak spot in the abdominal wall into the groin, appearing as a swelling or lump. Inguinal hernias can be repaired using surgery to push the bulge back into place. A mesh is placed in the abdominal wall, at the weak spot where the hernia came through, to strengthen it. Tissue adhesives (glues) can be used as an alternative to suture (stitches) for mesh fixation. The aim of this study is to assess the effectiveness of cyanoacrylate glue for hernia repair.

### Who can participate?

Patients aged 18 or over with an inguinal hernia

### What does the study involve?

Participants are randomly allocated to be treated with either a mesh fixed with sutures or a mesh fixed with glue. Participants are assessed for pain after 7 days, 1, 6 and 12 months, and are examined to see whether the hernia has come back (recurrence) at 2 years after surgery.

### What are the possible benefits and risks of participating?

Not provided at time of registration

### 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?

January 2007 to December 2011

### Who is funding the study?

Medical Canada (Spain)

### Who is the main contact?

Prof. Alfredo Moreno-Egea

## Contact information

### Type(s)

Scientific

**Contact name**

Prof Alfredo Moreno-Egea

**Contact details**

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## **Additional identifiers**

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

14186

## **Study information**

**Scientific Title**

Inguinal hernioplasty: tissue adhesive versus sutures: a randomized clinical trial

**Study objectives**

Is the adhesive tissue an alternative to the sutures for the inguinal hernioplasty? The use of tissue adhesives can be an alternative to suture fixation of the mesh, but their experience is very limited.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Ethics committee of Morales Meseguer University Hospital, 17/12/2006

**Study design**

Randomized prospective clinical 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**

Inguinal hernia

**Interventions**

Group 1 Lichtenstein operation (mesh fixed with sutures) and Group 2 mesh fixed with glue. The synthetic adhesive is n-hexyl- $\alpha$ -cyanoacrylate

**Intervention Type**

Procedure/Surgery

**Primary outcome measure**

Pain and recurrence. Patients were assessed for pain at 7 days, 1, 6 and 12 months using a visual analogue scale with a range from 0-10, and were examined clinically for recurrence at 2 year after surgery.

**Secondary outcome measures**

1. Operative time
2. Analgesic consumption
3. Hematoma
4. Infection

**Overall study start date**

01/01/2007

**Completion date**

30/12/2011

**Eligibility****Key inclusion criteria**

1. Patients with inguinal hernia not complicated
2. Patients (male and female) who were at least 18 years old and presented at the Abdominal Wall Unit of Morales Meseguer University Hospital of Murcia with a diagnosis of an inguinal hernia

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

120

**Key exclusion criteria**

Complicated hernias, bilateral and recurrent hernias

**Date of first enrolment**

01/01/2007

**Date of final enrolment**

30/12/2011

## **Locations**

**Countries of recruitment**

Spain

**Study participating centre**

Morales Meseguer University Hospital

Murcia

Spain

30008

## **Sponsor information**

**Organisation**

Medical Canada (Spain)

**Sponsor details**

Poligono Industrial

San Gines

Murcia

Spain

30500

**Sponsor type**

Hospital/treatment centre

**ROR**

<https://ror.org/011xgdn77>

## **Funder(s)**

### **Funder type**

Industry

### **Funder Name**

Medical Canada (Spain)

## **Results and Publications**

### **Publication and dissemination plan**

Not provided at time of registration

### **Intention to publish date**

### **Individual participant data (IPD) sharing plan**

### **IPD sharing plan summary**

Not provided at time of registration