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Is inguinal hernia repair possible with glue?

Submission date 09/01/2013	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 29/01/2013	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 20/09/2016	**Condition category** Digestive System	[_] Individual participant data [_] 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
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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-á-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