The Desarda and Lichtenstein Techniques in Inguinal Hernia Treatment.

Contemporary treatment of inguinal hernia is generally based on surgical methods with the use of synthetic meshes. The implanted meshes however have some disadvantages: they increase the risk of infection, tend to sustain inflammation process, can generate chronic pain and fertility disorders, can move from the initial implantation site, increase costs of treatment etc. The research to find any...

Date First Received: November 8, 2010

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Verified by: Nicolaus Copernicus University, July 2010

Clinical Trial Phase: N/A | Start Date: January 2005

Overall Status: Terminated

Estimated Enrollment: 2009

Brief Summary

Official Title: “The Desarda and Lichtenstein Techniques in Primary Hernia Treatment in Adult Males: Randomised, Multicenter, Blinded Study.”

Condition Keyword(s):

- Hernia, Inguinal

Additional Keyword(s) Provided by Sponsor:

- inguinal hernia
- hernia recurrence
- no mesh techniques
- Desarda technique

Intervention(s):

- Procedure: Desarda technique
- Procedure: Lichtenstein technique

Condition MeSH Term(s), Assigned with an Experimental Algorithm:

- Hernia
- Hernia, Inguinal

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sustain inflammation process, can generate chronic pain and fertility disorders, can move from the initial implantation site, increase costs of treatment etc. The research to find any new hernioplasty without the use of meshes is still going on.

Desarda in 2002 year published his own results over hernia treatment with the use of external oblique aponeurosis. These results were comparable with the effects of Lichtenstein technique.

The initial assessment done in our own department revealed good clinical results after hernia treatment with Desarda's method.

To make appropriate and objective clinical assessment of the Desarda's technique for primary inguinal hernia treatment the randomized multicentre double blinded clinical trial (RCT) was projected and conducted. Finally, 105 patients were included in the Desarda group and 103 in the Lichtenstein group. Personal clinical follow up was made up to 3 years after operation.

Generally no statistically significant differences were found between these groups. The only difference was higher rate of seroma after Lichtenstein technique and different pain perception in both groups. To the summary it is clear that Desarda technique is quite attractive and good proposition for operative hernia treatment without mesh. The RCT was done with the use of SharePoint Portal Server (Microsoft) which seems to be appropriate for clinical trials.

Study Type: Interventional

Study Design: Allocation: Randomized, Control: Active Control, Endpoint Classification: Efficacy Study, Intervention Model: Parallel Assignment, Masking: Double Blind (Subject, Investigator), Primary Purpose: Treatment

Study Primary Completion Date: June 2009

Intervention(s) in this Clinical Trial

- Procedure: Desarda technique
  - no mesh technique with undetached strip of external oblique aponeurosis placed at the floor of inguinal canal
- Procedure: Lichtenstein technique
  - hernioplasty with the usage of plain polypropylene mesh

Arms, Groups and Cohorts in this Clinical Trial

- Experimental: Desarda group
  - Patients with primary inguinal hernia operated using the Desarda technique
- Experimental: Lichtenstein group
  - Patients with primary inguinal hernia operated using the Lichtenstein technique.

Outcome Measures for this Clinical Trial

Primary Measures

- recurrence
  - Time Frame: 3 years
    Safety Issue?: No
- chronic pain

- Time Frame: 6 months
  Safety Issue?: No

Secondary Measures

- surgical complications
  - Time Frame: 3 years
    Safety Issue?: No

Criteria for Participation in this Clinical Trial

Inclusion Criteria:

- primary inguinal hernia
- male adults
- signed informed consent
- god condition of external oblique aponeurosis (assessed during the operation)

Exclusion Criteria:

- age < 18
- recurrent hernia
- incarcerated hernia
- diagnosed mental disorder
- manual reduction of hernia on inpatient
- infection at groin area
- wound or scar at the groin
- no consent

Gender Eligibility for this Clinical Trial: Male

Minimum Age for this Clinical Trial: 18 Years

Maximum Age for this Clinical Trial: N/A

Are Healthy Volunteers Accepted for this Clinical Trial?: No

Clinical Trial Sponsor Information

Lead Sponsor: Nicolaus Copernicus University Other

Overall Clinical Trial Officials and Contacts

Stanislaw Dabrowiecki, MD, PhD Study Chair Department of General and Endocrine Surgery, Collegium Medicum, Nicolaus Copernicus University Bydgoszcz, Poland

Related Publications

References

Desarda MP. Inguinal herniorrhaphy with an undetached strip of external oblique aponeurosis: a new approach used in 400 patients. Eur J Surg. 2001 Jun;167(6):443-8.

Desarda MP. Surgical physiology of inguinal hernia repair--a study of 200 cases. BMC Surg. 2003 Apr 16;3:2.

Additional Information

Information obtained from ClinicalTrials.gov on January 03, 2011

Link to the current ClinicalTrials.gov record. http://clinicaltrials.gov/show/NCT01237470

Study ID Number: Nicolaus Copernicus University

ClinicalTrials.gov Identifier: NCT01237470

Health Authority: Poland: Ethics Committee

Clinical Trials Authorship and Review

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