

Comparative study of a barbed suture, polyglecaprone and stapler in Pfannenstiel incisions performed for benign gynaecological procedures

Submission date 08/06/2009	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 09/07/2009	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 11/02/2010	Condition category Surgery	☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Study information

Scientific Title

Comparative study of a barbed suture, polyglecaprone and stapler in Pfannenstiel incisions performed for benign gynaecological procedures: a randomised trial

Study objectives

Are there any differences between three suture materials on post-operative incision pain, patient satisfaction and scar cosmesis?

Please note that as of 11/02/10 this trial has been updated to included participants aged 18-65.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee of the Dr. Lutfi Kirdar Kartal Research and Training Hospital approved on the 26th March 2009 (ref: 17/28.05.2009)

Primary study design

Interventional

Study design

Randomised controlled single centre trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Benign gynaecological diseases/skin incision closure

Interventions

This trial is taking place at the Istanbul Dr. Lutfi Kirdar Kartal Research and Training Hospital, Department of Obstetrics and Gynaecology. Approximately 117 patients will be recruited, 39 patients in each of the following three groups:

1. Skin incision closure with a barbed suture (copolymer of glycolide and e-caprolactone)
2. Skin incision closure with intracutaneous polyglecaprone
3. Skin incision closure with stapler

Patient allocation will be carried out as follows:

A computer based randomisation will be prepared. The skin closure type will be printed on identical sheets of paper, which will be put into identical, consecutively numbered sealed opaque envelopes by a non-participating colleague.

Intervention Type

Procedure/Surgery

Phase

Not Applicable

Primary outcome(s)

1. Pain for skin incision (post-operative third day)

Key secondary outcome(s)

1. Patient satisfaction (post-operative sixth day)
2. Scar cosmesis score (post-operative third month)

Completion date

31/12/2009

Eligibility

Key inclusion criteria

1. Women between ages of 18 - 45 years
2. Pfannenstiel incisions for benign gynaecological procedures
3. No previous lower abdominal incision

Amended 11/02/10:

1. Women between ages of 18 - 65 years

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Upper age limit

45 Years

Sex

Female

Key exclusion criteria

1. Previous lower abdominal incision
2. Diabetes mellitus
3. Body mass index more than 35 kg/m²
4. Chronic alcoholism

Date of first enrolment

01/06/2009

Date of final enrolment

31/12/2009

Locations

Countries of recruitment

Türkiye

Study participating centre
Cihat Saran Sk. Cagdas Apt. No:11/3
Istanbul
Türkiye
34841

Sponsor information

Organisation

Dr. Lutfi Kirdar Kartal Research and Training Hospital (Turkey)

ROR

<https://ror.org/01c2wzp81>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Dr. Lutfi Kirdar Kartal Research and Training Hospital (Turkey) - Department of Obstetrics and Gynaecology

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration