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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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

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)

Study design
Randomised controlled single centre 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
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 measure
1. Pain for skin incision (post-operative third day)

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

Overall study start date
01/06/2009

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
45 Years

Sex
Female

Target number of participants

Approximately 117

Key exclusion criteria
1. Previous lower abdominal incision
2. Diabetes mellitus
3. Body mass index more than 35 kg/m^2
4. Chronic alcholism

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
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34841

Sponsor information

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

Sponsor details
c/o Dr Mehmet Murat Naki
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Sponsor type
Hospital/treatment centre

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

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