ISRCTN85660082 https://doi.org/10.1186/ISRCTN85660082

The possible benefit of prophylactic antibiotic use in patients undergoing unilateral elective inguinal hernia repair with prosthetic material.

Submission date	Recruitment status	[_] Prospectively registered
21/01/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
04/03/2010	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
04/03/2010	Infections and Infestations	[_] 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
Prospective randomized controlled trial on the use of single dose antibiotic prophylaxis in patients undergo unilateral elective primary inguinal hernia repair with standard polypropylene mesh.

Study objectives
Tension-free repairs with prosthetic materials has lowered the recurrence rates in inguinal hernia repairs. As a foreign material polypropylene mesh may increase surgical site infection rate in early and late period. Some prospective randomised studies were done in this subject to reveal the benefit of antibiotic prophylaxis in these operations. However, no consensus does exist and every institution runs its own protocol to manage the cases.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Diskapi Teaching and Research Hospital Ethics Committee approved on the 24th of June 2009 (ref: 0016)

Study design
Prospective interventional double blind randomised active controlled trial.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet. (in Turkish)

Health condition(s) or problem(s) studied
inguinal hernia; surgical site infection; wound infection

Interventions
Eligible patients will be randomised by using sealed envelopes (equally numbered) to the control arm (no antibiotic prophylaxis) or to the intervention arm (antibiotic prophylaxis). The patients in the intervention arm will receive single dose intravenous cefazolin at the induction of anaesthesia. No topical antibiotic or antiseptic agents will be used within the surgical field after the repair is completed. No patients in either group will be given any additional antibiotic postoperatively. Dressings put in the operation room will be changed on day 1 and totally

removed on day 3. Control examination for infection follow-up will take place on day 1, day 3, day 7 and day 30. The late surgical site infection rates will be measured after one postoperative year for each patient and will be announced in a further report.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Surgical site infection:
1. Superficial infection
2. Deep infection

Secondary outcome measures
Components of the primary outcome:
1. Day of infection first recognised
2. Microbial culture for identification of the microorganism
3. Therapeutic antibiotic regimen according to antibiogram results
4. Final result for the wound and prosthetic material

Overall study start date
01/07/2009

Completion date
30/06/2010

Eligibility

Key inclusion criteria
1. Patients with primary unilateral hernia
2. Patients undergo unilateral primary hernia repair with a previously repaired or leave for interval repair on the contralateral side.
3. Age greater than 18 years, both female and male

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
200

Key exclusion criteria
1. Patients undergo simultaneous bilateral hernia repair
2. Patients with newly diagnosed or uncontrolled diabetes mellitus
3. Patients who do not accept the registry and randomisation
4. Incarcerated or strangulated hernias requiring emergency repair
5. Known severe coagulation disorder
6. Patients who use aspirin, clopidogrel (Plavix®) or warfarin (Coumadin®)
7. Recurrent hernias

Date of first enrolment
01/07/2009

Date of final enrolment
30/06/2010

Locations

Countries of recruitment
Türkiye

Study participating centre
Bahcelievler, 1.cadde, 109/5
Ankara
Türkiye
06490

Sponsor information

Organisation
Diskapi Teaching and Research Hospital (Turkey)

Sponsor details
c/o Hakan Kulacoglu, MD, FACS,
Associate Professor of Surgery
Department of Surgery
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Sponsor type
Hospital/treatment centre

Website
http://www.diskapieah.gov.tr/english.htm

ROR
https://ror.org/04bghze60

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Diskapi Teaching and Research Hospital (Turkey) - Department of Surgery

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