

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

Submission date 21/01/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 04/03/2010	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 04/03/2010	Condition category Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

Protocol serial number
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

Study type(s)

Prevention

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(s)

Surgical site infection:

1. Superficial infection
2. Deep infection

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration