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Topical antibiotic use in elective inguinal hernia repair

Submission date	Recruitment status	[ ] Prospectively registered
25/01/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
13/04/2010	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
13/04/2010	Digestive System	[ ] 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
Single dose intravenous antibiotic versus intravenous plus topical antibiotic prophylaxis in patients undergo elective unilateral inguinal hernia repair with polypropylene mesh.

Study objectives
Generally antibiotic prophylaxis is not recommended for pure suture-tissue repairs for inguinal hernias on elective basis. However, prophylaxis may be useful when prosthetic materials as a

foreign body are used. Single dose intravenous antibiotic prophylaxis may overcome the problem, but some centres are still experiencing high surgical site infection rates. Recently topical antibiotic use in addition to intravenous single shot have been examined.

Inguinal hernias consume a very big part of health resources. Surgical site infection, although not common, may increase that financial burden. Infection also is known to cause recurrence which is another element of further expenses.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The institution where the study will be done is a private centre with no ethical authority. The antibiotics to be used in the study are registered with the Turkish Health Authority.

Study design
Single centre 2 arm interventional study

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Inguinal hernia

Interventions
1. The routine prophylaxis group will receive single dose intravenous cephazolin.
2. The intervention group will also receive this shot. In addition, gentamycine will be used topically after the wound is irrigated with saline at the end of the repair before the subcutaneous tissue and the skin are closed.
Duration of follow up will be 30 days for postoperative infection rate and 1 year for late foreign body infection rate.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. Surgical site infection
2. Superficial and deep infection rates
All outcomes will be measured at postoperative days: 1, 3, 7 and 30

Key secondary outcome(s))
1. Features of the infection
2. Treatment of the infection

3. Microbial culture and antibiogram
4. Financial portrait of the infection
All outcomes will be measured at postoperative days: 1, 3, 7 and 30

Completion date
01/11/2010

Eligibility

Key inclusion criteria
1. Primary unilateral inguinal hernia
2. Recurrent unilateral inguinal hernia
3. Elective repair
4. Male or female

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
Bilateral hernia repair

Date of first enrolment
01/02/2010

Date of final enrolment
01/11/2010

Locations

Countries of recruitment
Türkiye

Study participating centre
Cukurambar mahallesi, 38.cd. 33/A
Ankara
Türkiye
06520

Sponsor information

Organisation
Ankara Hernia Centre (Turkey)

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Ankara Hernia Centre (Turkey)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes