

Topical antibiotic use in elective inguinal hernia repair

Submission date 25/01/2010	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 13/04/2010	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 13/04/2010	Condition category Digestive System	☐ 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

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.

Primary study design

Interventional

Study design

Single centre 2 arm interventional study

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