

Topical antibiotic use in elective inguinal hernia repair

Submission date 25/01/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 13/04/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 13/04/2010	Condition category Digestive System	<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

Contact name
Dr Ipek Ozyaylali

Contact details
Cukurambar mahallesi, 38.cd. 33/A
Ankara
Türkiye
06520

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Prevention

Participant information sheet

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

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 measure

1. Surgical site infection
 2. Superficial and deep infection rates
- All outcomes will be measured at postoperative days: 1, 3, 7 and 30

Secondary outcome measures

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

Overall study start date

01/02/2010

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

Age group

Adult

Sex

Both

Target number of participants

100 in total, in 2 arms

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)

Sponsor details

Cukurambar mahallesi, 38.cd. 33/A

Ankara

Türkiye

06520

Sponsor type

Hospital/treatment centre

Website

<http://www.herniaturk.org>

Funder(s)**Funder type**

Hospital/treatment centre

Funder Name

Ankara Hernia Centre (Turkey)

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