Clinical Trial Protocol
Iranian Registry of Clinical Trials

23 Sep 2026

Comparison the effect of two days interval amikacin with standard therapy in treatment of urinary tract infection

Protocol summary

Study aim

1-Determination of the effect of amikacin on two-day intervals on ESBL E.coli in the intervention group 2. Determine the effect of standard treatment on ESBL E.coli in the control group 3. Determination of the effect of amikacin on two-day intervals on non ESBL Ecoli in the intervention group 4- Determination of the effect of Standard on non ESBL Ecoli in the control group

Design

People who come to the Tohid Hospital with burning symptoms, frequencies, or fever undergo a smear test and urine analysis and culture. And the names of all of them are recorded. After the patient has been diagnosed with urinary tract infections and confirmed by an infectious disease physician, the patient is included in the study. Individuals who entered the randomly-assigned blocks with 20 blocks in one of the two new treatment groups and the two control groups Usually). Considering that at the beginning of the study urine sample should be cultured and after the culture, the group should be identified, but based on ethical principles, patients can not be left without treatment during the first few days, therefore, from the beginning, randomization is done and after The result of the cure will continue treatment in the same group. Therefore, considering that about 64% of ESBL (Expended expectrum beta lactamases) patients are positive, therefore, for access to 50 patients in each group, 160 patients need to be examined in order to finally receive a 50-member ESBL positive group in each intervention group and 30 patients In each group, ESBL will remain negative, and each will receive one kind of intervention. But the main goal of the study is to compare the two groups of 50. To compensate for possible dropouts, 200 people will be examined. After group treatment, protocol treatment is given to each group (one group of meropenem and one group of amikacin). The drug is prescribed by microset. The new treatment will receive 3mg / kg of amikacin every 48 hours and the control group will receive 1gr / TDS of meropenem every 8 hours. Blind for each group is injected through the microset at intervals of 8 hours, in the intervention group, additional injections contain distilled water, which is poured into normal saline containing microset. Medicines are placed in the patient basket by category. And the nurse will run the daily basket in accordance with its instructions. Given that the assessor, the laboratory, and the patient are unaware of any grouping, the study is virtually double blind.

Settings and conduct

After determining the treatment group, the treatment is given to each group based on the protocol (one group of meropenem and one group of amikacin). The drug is administered via microset. The new treatment group receives amikacin at 3mg / kg / Q48 hours. The control group receives 1 µg / TDS of meropenem every 8 hours. Blind for each group is injected through the microset at intervals of 8 hours, in the intervention group, additional injections contain distilled water, which is poured into normal saline containing microset. Medicines are placed in the patient basket by category. And the nurse will run the daily basket in accordance with its instructions. Given that the assessor, the laboratory, and the patient are unaware of any grouping, the study is virtually double blind.

Participants/Inclusion and exclusion criteria

Entry criteria: Patients with signs of burning and frequent urination or fever Exit criteria: 1.use of antibiotics over the last week 2. Patients at stage I and above CKD(chronic kidney diseases) 3.pregnancy 4.septic shock 5.use of immuno suppressive drugs 6.Increased patient creatinine by more than 3 or more than 50% relative to the original creatinine during treatment

Intervention groups

1.ESBL intervention (50 people):In a group of patients who are ESBL-positive Each 48 hours of amikacin is given 3mg / kg for 7 days and then treatment of 300 mg of ofloxacin twice daily for 7 days. At the end of the initial initial injection, clinical symptoms are recorded and urine analysis and culture tests are performed. 2. Non-ESBL

intervention (30 people):In a group of patients who are non-ESBL-positive Each 48 hours of amikacin is given at 3mg / kg for 7 days. Then the treatment with ofloxacin 300 mg twice daily for 7 days is continued. At the end of the initial initial injection, clinical symptoms are recorded and a urine analysis and culture test is performed. 3. ESBL control (50 peaple): INn ESBL control group patients Meropenem is given at a dose of 1 g three times a day for one week, followed by treatment with ofloxacin 300 mg twice daily for 7 days. 4. NON ESBL control (30 peaple): In non-ESBL control group patients Meropenem is given at a dose of 1 g three times a day for one week, followed by treatment with ofloxacin 300 mg twice daily for 7 days.

Main outcome variables

Treatment of urinary tract infection in patients with positive culture of E. coli during admission

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170417033483N2**
Registration date: **2018-02-13, 1396/11/24**
Registration timing: **registered_while_recruiting**

Last update: **2018-02-13, 1396/11/24**
Update count: **0**

Registration date

2018-02-13, 1396/11/24

Registrant information

Name

Hero Azizzadeh

Name of organization / entity

Kurdistan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 87336646456

Email address

h.azizzadeh@muk.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor University of Medical Sciences Kzdstan

Expected recruitment start date

2017-05-22, 1396/03/01

Expected recruitment end date

2018-04-21, 1397/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of two days interval amikacin with standard therapy in treatment of urinary tract infection

Public title

Comparison the effect of two days interval amikacin with standard therapy in treatment of urinary tract infection

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with symptoms of burning up urine Patients with frequent urinary symptoms Patients with urinary symptoms and fever

Exclusion criteria:

Use of antibiotics over the last week Stage I and above CKD pregnancy septic shock use of immuno suppressive drugs Increased patient creatinine by more than 3 or more than 50% relative to the original creatinine during treatment

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **200**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients with inclusion criteria are randomly assigned to blocks of 20 in one of the two new treatment groups and the two control groups (routine treatment).

Blinding (investigator's opinion)

Double blinded

Blinding description

After determining the treatment group, the treatment is given to each group based on the protocol (one group of moropenem and one group of amikacin). The drug is administered via micro-nutrition. The new treatment group receives 48 hours of amikacin at 3mg / kg / Q48 hours. The control group receives 1 µg / TDS of morophen every 8 hours. Blind for each group is injected through the microscope at intervals of 8 hours, in the intervention group, additional injections contain distilled water, which is poured into normal saline containing microscope. Medicines are placed in the patient basket by category. And the nurse will run the daily basket in accordance with its instructions. Given that the assessor, the laboratory and patient are not aware of any grouping.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
University of Kurdestan Medical Sciences, Faculty of Medicine

Street address
Sanandaj, Kurdistan-Kurdistan-Iran Iranian Revolutionary Guards University of Medical Sciences

City
sanandaj

Province
Kurdistan

Postal code
66177-13446

Approval date
2016-10-30, 1395/08/09

Ethics committee reference number
MUK.REC.1395.197

Health conditions studied

1

Description of health condition studied
UTI

ICD-10 code
N39

ICD-10 code description
Urinary tract infection, site not specified

Primary outcomes

1

Description
Urinary tract infection(UTI)

Timepoint
7 days after the start of treatment, intravenous and oral treatment phase (7 days

Method of measurement
Urine analysis and urina culture

2

Description
Clinical symptoms of UTI

Timepoint
48 hours and 1 week after the end of therapy with intravenous and oral treatment

Method of measurement
By patient symptoms and clinical findings

Secondary outcomes

1

Description
Adverse Drug Reactions

Timepoint
48 hours and 1 week after treatment and at the end of intravenous and oral treatment

Method of measurement
Clinical symptoms and examination findings, laboratory

Intervention groups

1

Description
Intervention group ESBL: Each 48 hours of amikacin is given 3mg / kg / Q48 hours for 7 days, and then treatment of Ofloxacin 300 mg twice daily for 7 days is continued.

Category
Treatment - Drugs

2

Description
ESBL control group: INn ESBL control group patients Maropenem is given at a dose of 1 g three times a day for one week, followed by treatment with ofloxacin 300 mg twice daily for 7 days.

Category
Treatment - Drugs

3

Description
Control group NON ESBL: In non-ESBL control group patients Maropenem is given at a dose of 1 g three times a day for one week, followed by treatment with ofloxacin 300 mg twice daily for 7 days.

Category
Treatment - Drugs

4

Description
Non ESBL intervention group: Each 48 hours of amikacin is given 3mg / kg / Q72 hours for 7 days, then treatment with ofloxacin 300 mg twice daily for 7 days.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Tohid Hospital in Sanandaj

Full name of responsible person
hero azizzadeh

Street address
sanandaj,tohid hospital
City
sanandaj
Province
Kurdistan
Postal code
6616812131
Email
heroazizzadeh@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kurdistan university of Medical Sciences
Full name of responsible person
Dr Farzin Rezaei
Street address
Kurdistan university of Medical Sciences,pasdaran street,sanandaj
City
sanandaj
Province
Kurdistan
Postal code
6616812131
Email
heroazizzadeh@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kurdistan university of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Kurdistan University of Medical Sciences
Full name of responsible person
hero azizzadeh
Position
Medical student
Latest degree
Medical doctor
Other areas of specialty/work
Street address
Kurdistan University of Medical Sciences, pasdararn street , Sanandaj
City
sanandaj
Province
Kurdistan
Postal code
666147 - 13446
Phone
+98 87 3366 4645
Fax
Email
h.azizzadeh@muk.ac
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
kurdistan University of Medical Sciences
Full name of responsible person
Dr.behzad mohsenpour
Position
infectious disease specialist
Latest degree
Specialist
Other areas of specialty/work
Street address
Kurdistan University of Medical Sciences, Pasdaran Boulevard, Sanandaj, Kurdistan
City
sanandaj
Province
Kurdistan
Postal code
666147 - 13446
Phone
+98 87 3366 4645
Fax
Email
behzadmohsenpour@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Kurdistan University of Medical Sciences
Full name of responsible person
hero azizzadeh
Position
Medical student
Latest degree
Medical doctor
Other areas of specialty/work
Street address
Kurdistan, Pasdaran Boulevard, Kurdistan University of Medical Sciences
City
sanandaj

Province
Kurdistan
Postal code
66177-13446
Phone
+98 87 3366 4645
Fax
Email
h.azizzadeh@muk.ac
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available