Study Design Of Medical Research

By

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Study Designs In Medical Research

Topics

- Classification
- Case – series studies
- Case – control studies
- Cross- sectional studies
- Cohort studies
- Interventional or Experimental studies
- Summary
- Exercises
Study Designs In Medical Research

Classification

-2 Basic Types

Observational
- Subjects are observed
- No intervention

Interventional or Experimental
- Intervention is done
- Effect of interv. observed

-Unclassified Type
Meta-analysis

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Classification
Observational Studies

4 Types

1) Case – series
2) Case – control
3) Cross – sectional
4) Cohort
Classification
Observational Studies

- Initial Step
- Generate Hypothesis

Case – series Studies

- The simplest design
- Author describes some interesting observations
- A small number of patients
- Leading to generation of hypothesis

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Classification
Observational Studies

- Hypothesis generated by case – series studies are further investigated by the other 3 types of observational studies depending upon 2 factors :

1- Duration of Time
2- Direction of Time
Classification
Observational Studies
Types

1- Duration of Time

One time only
- Cross – Sectional Study

Extended period of time
- Case – control
- Cohort
- Longitudinal
Classification
Observational Studies

Types

2- Direction of Time

Simultaneous Event
- Today
  - Survey
  - Cross-sectional

Backward Looking
- Yesterday
  - From outcome to risk factors
  - Case-control

Forward Looking
- Tomorrow
  - From risk factors to outcome
  - Cohort
Time relationship among observational studies

- **TODAY**:
  - Survey
  - Cross-sectional
  - Cohort

- **YESTERDAY**: Case-control

- **TOMORROW**:

Direction of Time: YESTERDAY → TODAY → TOMORROW
# Time Relationship Among Observational Studies

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Meta-analysis
Classification

Interventional or Experimental

Controlled
- Parallel or Concurrent
  - Randomized
  - Nonrandomized

Noncontrolled
- Sequential
  - Self–control
- Historical
  - Cross over

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Case –series Studies

- **Characters**
  - A simple descriptive account of interesting observations in a small group of patients.
  - Generates hypothesis.
  - There is no control.
  - Covers only a short time.
Case – series Studies

- **Advantages**
  1) Easy to write
  2) May provide extremely useful information to investigators designing a larger well-designed study.

- **Disadvantages**
  - Liable to many possible biases related to subject selection and characteristics.
  - Should be viewed as hypothesis – generating and not as conclusive.
Case – series studies

Example

Ghoneim and coworkers (2011) presented information in a series of 20 adult patients with nocturnal enuresis. The authors wanted to investigate the correlation between the depth of sleep and the degree of nocturnal enuresis. They concluded that the relationship between the depth of sleep and the degree of nocturnal enuresis is very strong.
Case – series studies

Example

- Small number → 20 patients
- Description of interesting observation → Nocturnal enuresis in adults.
- Generates hypothesis → correlation between degree of enuresis and depth of sleep.
- No control.
- Covers a short time.
General Information

Each study contains 2 important points

Start point  

Item under investigation

End point  

Outcome

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General information

Practical Example

- Prolonged use of birth control pills (BCP) may increase the risk of development of breast cancer (Br Ca). This example will be used to clarify the different types of studies.
General Information

Practical Example
BCP vs. Br Ca

Item Under Investigation  BCP

Outcome  Br Ca
Study Designs In Medical Research

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- Exercises
Case-control Study

Definition:
- The study contains 2 groups:
  - Case group: contains the disease.
  - Control group: does not contain the disease.

Characters:
- Always controlled
- Always retrospective (Backward looking)
- Covers extended period of time (longitudinal)
- Answers the question: “What happened?”

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Ghoneim and associates (2011) compared 100 middle-aged women with breast cancer (Br Ca) versus 100 aged – matched women with no Br Ca. The authors wanted to investigate the association between prior use of birth control pills (BCP) and Br Ca. The authors concluded that a strong association is observed between prior use of BCP and Br Ca.
Case – control study design
“Practical Example”

Question: How did the use of birth control pills (BCP) affect Breast cancer?

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Case – control study design

Exposed

Unexposed

Exposed

Unexposed

2006

2011

onset of study

Time

Backward looking

Direction of inquiry

Question “What Happened”
Case – control Study

- At start of the study the authors already know the outcome (Br Ca).

- Then they study the item under investigation (BCP).

- The authors go backward in time to study the correlation between the outcome (Br Ca) and the item under investigation (BCP).
Case- control studies

- Advantages

  - The quickest and least expensive.
  - Ideal for investigators who need preliminary data prior to writing a proposal for a more complete, expensive, and time-consuming study.
  - Good choice for someone who needs to complete a clinical research project in a short time.
Case – control Studies

- Disadvantages
  - Of all study methods, they have the largest number of possible biases or errors.
  - They depend completely on high quality exiting records.
  - Many of the required data may not be available at the time of writing article.
  - Great difficulty in choosing the controls who are similar to the cases.
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Cross - sectional Studies

- Names
  - Cross- sectional
  - Surveys
  - Epidemiologic
  - Prevalence
Cross – sectional Studies

- **Characters**
  - Analyze data collected on a group of subjects at one time rather than over a period of time.
  - Answer the question: “What is happening right now”
Question: “What is the prevalence of breast cancer right now in middle-aged women?”
Cross-sectional Study Design

Subjects selected for the study

With outcome

Without outcome

2011
Time
onset of study

No Direction of Inquiry
Question “What is happening?”

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Cross – sectional Study Design

- The item under study (BCP) and the outcome (Br Ca) are studied at the same time.

- There is no direction of time.
Cross – sectional Studies

- **Indications**
  The best for determining the status of a disease or a condition such as HIV in a given population.

- **Advantages**
  Similar to case – control studies being quick and inexpensive

- **Disadvantages**
  - Provide only a “snapshot in time” of a disease or process which may be misleading.
  - Many people asked to participate in a survey decline because they are busy or not interested. So the sample may not be representative to the entire population.
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Cohort Studies
Meaning of the word cohort

- OXFORD DICTIONARY
  - A group of people united in supporting an idea, a person, etc.
  - A colleague
  - A companion

- MEDIACL STUDIES
  - A cohort is a group of individuals who share a common experience.

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Cohort Studies

- Concurrent “Typical”
- Nonconcurrent “Historical” “Data Base”
Concurrent “Typical” cohort studies

- Individuals are observed over time to determine their outcome.
- It is called concurrent because individuals are monitored concurrently over time.
Cohort Study Design
Typical “concurrent”
Practical Example

Middle aged women

2011
Onset of study

2016
Time

Question: “How will the use of birth control pills (BCP) affect prevalence of breast cancer in middle-aged women?”

Already Using BCP
Breast cancer
No Breast cancer

Already Not using BCP
Breast cancer
No breast cancer
Cohort Study Design

Typical “concurrent”

Subjects already (exposed)

With outcome

Without outcome

Control already (unexposed)

With outcome

Without outcome

Cohort selected for the study

2011

Onset of study

2016

Time

Forward looking from now and forward

Direction of inquiry

Question: “What will happen”?
Concurrent “Typical” cohort study

- At start of the study the authors do not know the outcome (Br Ca).

- Then they study the item under investigation (BCP).

- The authors go forward in time to correlate between the item under investigation (BCP) and the outcome (Br Ca).
Cohort studies

- Concurrent
  - “Typical”
- Nonconcurrent
  - “Historical”
  - “Data Base”
Historical (Non concurrent) Cohort Study design
Practical Example

Records of middle-aged women

BCP users

Breast cancer
No Breast cancer

BCP Nonusers

Breast cancer
No Breast cancer

2006
Onset of study

2011
Time

Forward looking from the past (2006) to the present (2011)

Direction of inquiry
Historical Cohort (Nonconcurrent Cohort) Study Design

Records selected for the study

Subjects already (exposed)

With outcome

Without outcome

Control already (unexposed)

With outcome

Without outcome

2006

Onset of study

2011

Time

Forward looking from the past to the present time

Direction of inquiry
Nonconcurrent “Historical” cohort studies “Data Base Research”

- It is nonconcurrent because individuals are not observed over time to determine the outcome, but the outcome is determined at the same time the individuals are assigned to the study.

- It is still cohort study because at the time the individuals are assigned to the study the investigator does not know the outcome.
Cohort studies

- Indications
  - Because they are longitudinal and follow a group of subjects over a prolonged period, they are the design of choice for studying the risk factors.
Comparison of case – control and cohort studies

Cohort Studies

- A cohort study begins by identifying a cohort that posses the item under study (using BCP) as well as a cohort that does not possess that particular item (NOT using BCP).

- Then the frequency of disease (Br Ca) [the outcome] in the 2 cohorts is obtained and compared.
Comparison of case – control and cohort studies

Case – control Studies

- Case-control study begins by the fact that the investigator already knows that the study group (case group) already has the disease (Br Ca) and the control group DOES NOT have the disease.

- Then the item under investigation (prior use of BCP) is calculated in case versus control groups.
Comparison of case – control and cohort studies

Concurrent cohort study
- 100 women already using BCP
- 100 women already not using BCP
- Start follow up

Assessment of Br Ca
- Check files of 2006
- 100 women already using BCP
- 100 already not using BCP
- Assess Br Ca

Non concurrent cohort study
- Check files OF 2006
- 100 women with Br Ca
- 100 with no no Br Ca
- Assess for taking BCP

Case - control study
- 100 women with Br Ca
- 100 with no Br Ca
Time relationship among observational studies

- **TODAY**
  - Survey
  - Cross-sectional
  - Cohort
  - Case-control

- **YESTERDAY**
  - Historical Cohort

- **TOMORROW**

**Direction of Time**

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Study Designs In Medical Research

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- Classification
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- Cross- sectional studies
- Cohort studies
- Interventional or Experimental studies
- Summary
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Interventional or Experimental Studies

- **General features**
  - They include intervention. Then, the results of intervention are observed.
  - Could be carried out on human “clinical” or animals.
Classification

Interventional or Experimental

Controlled

- Concurrent
  - Randomized
  - Nonrandomized

- Sequential
  - Self - control

Non controlled

- Historical
  - Cross over
Randomized Clinical Trial (RCT) Example

- Group of Women
- Intervention
- Randomization
  - Study: Give BCP
  - Control: Don’t Give BCP

Follow-up: Probability of Br Ca
RCT Study Design
Practical Example

Middle aged women

Randomization

Give BCP

Breast cancer

No Breast cancer

Don't give BCP

Breast cancer

No Breast cancer

Onset of study

2011

Give BCP or don't give BCP

2016

Assess Br Ca

Time
RCT Study Design

Subjects meeting entry criteria

Randomization

Experimental subjects

Without outcome

With outcome

Controls

Without outcome

With outcome

2011

Onset of study

Intervention

XXXXXX

2016

Study outcome

Time

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Cohort Study Vs Randomized Clinical Trial

- In cohort study there is no intervention. The item under study is already existing and observation is done forward in time.
- In RCT there is intervention through deciding to give or not to give the item under study, then observation is done forward in time.
- In RCT decision to give or not to give the item under study is taken by randomization.
Randomized Clinical Trials (RCT)

- Types of controls in RCT

  1) Gold standard, reference standard, or standard of care.
  2) Placebo
  3) Sham
Randomized Clinical Trials
Types of Controls

1) Gold standard. “passed the test of time”.

- **Treatment Modality:**
  - Medication.
  - Surgical procedures.

- **Diagnosis Modality:**
  - Radiological.
  - Endoscopic.
  - Histopathological.
Randomized Clinical Trials
Types of Controls

2- Placebo

- Used in pharmaceutical studies.
- The drug under investigation is tested against a phantom having the same shape, color, weight, and taste but having no effective material.
- Placebo is important to nullify the psychological effect of receiving the treatment.
Randomized Clinical Trial (RCT)

Types of Controls

3- Sham Operations

- Used in surgical experimental studies.
- The animal is opened, the concerned organ is identified and dissected, then the wound is closed.
- Sham operations is important to nullify the effect of anesthesia, incision and closure of all wound layers.
Randomized Clinical Trial (RCT)  
How To Do Randomization

The most common:

- Closed envelop

- Computer generated random tables.
Randomized Clinical Trials (RCT)

- **Indications**
  - The best type to use when the objective is to establish the efficacy of a treatment or a procedure.

- **Advantages**
  - It is the gold standard or reference in medicine.
  - It provides the greatest justification for concluding the cause and effect.
  - It is subject of least number of biases.

- **Disadvantages**
  - Expensive
  - Needs a long time for follow up.
# Randomized Clinical Trials (RCT)

<table>
<thead>
<tr>
<th>Types</th>
<th>Patient</th>
<th>Doctor</th>
</tr>
</thead>
<tbody>
<tr>
<td>1- Open-label</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>2- Blind</td>
<td>X</td>
<td>✓</td>
</tr>
<tr>
<td>3- Double Blind</td>
<td>X</td>
<td>X</td>
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</table>
Randomized Clinical Trials
Open-label Study
Example

A group of authors conducted a RCT of 100 patients of benign prostatic hyperplasia. Patients were randomized into 2 equal groups: group A received a gold standard $\alpha$-1a blocker (tamsulosin) and group B received a new $\alpha$-1d blocker (Naftopidil). All patients know the type of treatment received. Follow-up was carried out by the same doctors who already know the type of treatment received by each patient.
A group of authors conducted a RCT of 100 patients of benign prostatic hyperplasia. Patients were randomized into 2 equal groups; group A (50 patients) received $\alpha$ – blocker (Tamsulosin) and group B (50 patients) received placebo. All patients did not know the type of treatment received. Patients were followed by the same group of doctors conducting the study who know the type of treatment received by each patient.
Randomized Clinical Trials
Double Blind Study
Example

A group of authors conducted a RCT of 100 patients of benign prostatic hyperplasia. Patients were randomized into 2 equal groups; group A (50 patients) received α-blocker (Tamsulosin) and group B (50 patients) received placebo.

All patients did not know the type of treatment received. Patients of both groups were followed up by a doctor not sharing in the study and was not aware of the kind treatment received by each patient.

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Classification

Interventional or Experimental

Controlled
- Concurrent
  - Randomized
  - Nonrandomized
- Sequential
- Historical

Non controlled
- Self – control
- Cross over
Trials With Self Controls

- **Description**
  - The same group of patients is used for both experimental and control options.
  - e.g. Before and after treatment.

- **Practical Example**

  The study by Ghoneim et al (2011) involved 100 patients with lower urinary symptoms (LUTS) due to benign prostatic hyperplasia (BPH). All patients were subjected to medical treatment using α – blocker tamsulosin. The authors evaluated their patients using AUA symptom score before treatment and at 1 and 3 months after treatment. The authors concluded that the use of tamsulosin improves the AUA symptoms score of patients suffering from LUTS due to BPH.
Classification

Interventional or Experimental

Controlled
  - Concurrent
    - Randomized
    - Nonrandomized
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    - Self - control
  - Historical
    - Cross over

Non controlled
Cross over study

- 2 groups: one experimental and one control

- Experimental group is given treatment and control group is given placebo.

- After a time, the experimental and control groups are withdrawn from both groups for a “washout” period during which both groups receive no treatment.

- The groups are then given the alternative treatments; the first group receives placebo and the second group receives the experimental treatment.

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A group of authors conducted a study including 100 patients with lower urinary tract symptoms (LUTs) due to benign prostatic hyperplasia (BPH). The first consecutive patients (group A) were given α – blocker (Tamsulosin) and the subsequent consecutive 50 patients (group B) were given placebo. International prostate symptom score (IPSS) was compared among both groups after 6 weeks of continuous treatment.
The treatment was stopped for 2 weeks and the type of treatment in both groups was reversed: group A patients who were receiving tamsulosin received placebo and group B patients who were receiving placebo received Tamsulosin. IPSS was compared among both groups after 6 weeks of continuous treatment.
Classification

Interventional or Experimental

Controlled

- Concurrent
  - Randomized
  - Nonrandomized

- Sequential
  - Self-control
  - Cross-over

Non-controlled

- Historical
Trials with External or Historical Control

- The third method for controlling experiments is to use controls external to the study.

- This may include:
  - Results of other investigators
  - Previous results of the same investigator (Historical).
Trials with External or Historical Control

Example

- A group of authors conducted a study including 100 patients with BPH who were treated by laser prostatectomy (study group). At 1 year of follow-up the authors compared the results of these 100 patients with the results of other 100 patients with BPH who were previously treated 2 years ago by the same authors using the conventional transurethral resection of the prostate (control group).
Study Designs In Medical Research

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  - Subjects are observed
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Interventional or Experimental
  - Intervention is done
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-Unclassified Type

Meta – analysis
Meta-analysis Study

- **Definition:**
  Combining data from 2 or more existing studies.

- **Importance**
  - The most accurate way to draw a conclusion.
  - Helps overcome diversity of the results of different studies.

- **Application**
  More appropriate to review articles.
Masking

- Masking of study subjects and investigators is an important part of the assignment of patients in a RCT.

- Single Masking “Blind Study”
  Implies that the patient is not aware of which therapy is being received.

- Double Masking “Double Blind Study”
  Implies that neither the patient nor the investigator aware of group assignment.

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Study Designs In Medical Research

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- Cross-sectional studies
- Cohort studies
- Interventional or Experimental studies

Summary

Exercises
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4 Types

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Classification

Observational Studies

Initial Step → Generate Hypothesis

Case – series Studies

- The simplest design
- Author describes some interesting observations
- A small number of patients
- Leading to generation of hypothesis
- Hypothesis generated by case–series studies are further investigated by the other 3 types of observational studies depending upon 2 factors:

1. Duration of Time
2. Direction of Time
Classification
Observational Studies
Types

1- Duration of Time

- One time only
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  - Cohort
  - Longitudinal
Classification
Observational Studies
Types

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Forward Looking
Tomorrow
- From risk factors to outcome
  - Cohort
Time relationship among observational studies

- **TODAY**
  - Cohort
  - Survey (Cross-sectional)

- **YESTERDAY**
  - Case-control
  - Historical Cohort

- **TOMORROW**
  - Direction of Time

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Exercises

1) Ghoneim and coworkers (2011) presented information in a series of 20 patients who had been referred for evaluation of stroke or transient ischemic attack. The authors wanted to test the accuracy of a new method to predict peak systolic velocity. They concluded that the new method is very accurate.

The design of the above study is:

- a- Case – series
- b- Case – control
- c- Cross sectional
- d- Cohort
- e- Randomized clinical trial
2) Ghoneim et al (2011) compared 100 patients who had surgical site infection following laminectomy with 100 matched patients who developed no infection. Data were retrieved from the patients files. The investigators found that length of hospital stay and readmission rates were greater with patients with infection. Furthermore, postoperative incontinence was one of the risk factors associated with the development of infection.

The design of the above study is:

a- Cross sectional
b- Cohort
c- Case – control
d- Randomized clinical trial
e- Case – series

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The study by Ghoneim et al (2011) involved patients who underwent cholecystectomy. Patients were evaluated preoperatively and at 1, and 3 months after cholecystectomy. Changes such as abdominal pain, flatulence and dyspepsia were compared in the same patients before and after surgery.

The design in the above clinical study is:

a- Randomized clinical trial
b- Self-controlled clinical study
c- Clinical study with historical control
d- Crossover study
4) Ghoneim and coworkers (2011) designed a study to determine the efficacy of immunotherapy with ant venom for treating ant stings. The study involved a group of 68 adults who were allergic to ant stings; each subject was randomly assigned to receive either venom immunotherapy or a placebo. After a sting challenge in which any reactions were recorded, the group originally on the placebo was given the venom immunotherapy, and after a sufficient time, they too were given a sting challenge.

The design of the above clinical study is:

a- Crossover study
b- Cross sectional study
c- Case – series study
d- Case – control study
5) Ghoneim et al (2011) wanted to compare prevalence of infertility among married couples of Qatari and non Qatari people. They sent a questionnaire to 5000 couples of each group, of whom 2000 Qatari and 3000 non Qatari people responded. The authors concluded that there was no significant difference in the prevalence of infertility among Qatari and non Qatari people.

The design of the above study is:

a- Crossover
b- Cross – sectional
c- Case - control
d- Concurrent cohort
e- Nonconcurrent cohort
6- A group of authors wanted to study the association between schistosomiasis and squamous cell carcinoma of the bladder. The authors chose 100 patients with squamous cell carcinoma and 100 aged and sex matched people with nonspecific cystitis from the database of the hospital. The authors determined the percentage of patients with and without schistosomiasis in both groups and found a statistically higher proportion of schistosomal affection in patients with squamous cell carcinoma.

The design of the above study is:

- Concurrent cohort
- Nonconcurrent cohort
- Case – control study
- Randomized clinical trial
7- At 2011, a group of authors checked the files of 2006 and chose 1000 smokers and 1000 aged and sex matched nonsmokers. At 2011 the authors called the 2 groups and examined them for the possibility of lung cancer. The authors found a significantly higher prevalence of lung cancer among smokers.

The design of the above study is:

a- Case - control
b- Concurrent cohort
c- Nonconcurrent cohort
d- Randomized clinical trial
8- A group of authors chose 500 patients with hyperuricaemia and a similar number of age and sex matched persons with normal serum uric acid. The authors followed both groups for the possibility of occurrence of urinary stones. Follow-up included renal ultrasonography every 6 months. After 6 years of follow up the authors demonstrated a statistically significant higher incidence of renal stones in hyperuricaemic group.

The design of the above study is:

a- Randomized clinical trial
b- Case - control
c- Concurrent cohort study
d- Nonconcurrent cohort study
A group of 100 patients with lower ureteral stones were randomly assigned to receive doxazosin (α blocker) (50 patients) or placebo (50 patients). Patients were followed up for 4 weeks by plain abdominal x-ray and ultrasonography. Patients receiving α blocker had significantly higher proportion of spontaneous stone passage compared with the placebo group.

The design of the above study is

a- Case - control
b- Randomized clinical trial
c- Concurrent cohort study
d- Nonconcurrent cohort study
10- In which of the following study designs masking is suitable to avoid selection bias:

a- Case - control studies

b- Concurrent cohort studies

c- Nonconcurrent cohort studies

d - Randomized clinical trial
1) Ghoneim and coworkers (2011) presented information in a series of 20 patients who had been referred for evaluation of stroke or transient ischemic attack. The authors wanted to test the accuracy of a new method to predict peak systolic velocity. They concluded that the new method is very accurate.

The design of the above study is:

- **a**- Case – series
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- **d**- Cohort
- **e**- Randomized clinical trial
2) Ghoneim et al (2011) compared 100 patients who had surgical site infection following laminectomy with 100 matched patients who developed no infection. Data were retrieved from the patients files. The investigators found that length of hospital stay and readmission rates were greater with patients with infection. Furthermore, postoperative incontinence was one of the risk factors associated with the development of infection. The design of the above study is:

- a- Cross sectional
- b- Cohort
- c- Case – control
- d- Randomized clinical trial
- e- Case – series
3) The study by Ghoneim et al (2011) involved patients who underwent cholecystectomy. Patients were evaluated preoperatively and at 1, and 3 months after cholecystectomy. Changes such as abdominal pain, flatulence and dyspepsia were compared in the same patients before and after surgery.

The design in the above clinical study is:

a- Randomized clinical trial

b- Self - controlled clinical study

c- Clinical study with historical control

d- Crossover study
4) Ghoneim and coworkers (2011) designed a study to determine the efficacy of immunotherapy with ant venom for treating ant stings. The study involved a group of 68 adults who were allergic to ant stings; each subject was randomly assigned to receive either venom immunotherapy or a placebo. After a sting challenge in which any reactions were recorded, the group originally on the placebo was given the venom immunotherapy, and after a sufficient time, they too were given a sting challenge.

The design of the above clinical study is:

- **a)** Crossover study
- **b)** Cross sectional study
- **c)** Case – series study
- **d)** Case – control study

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5) Ghoneim et al (2011) wanted to compare prevalence of infertility among married couples of Qatari and non Qatari people. They sent a questionnaire to 5000 couples of each group, of whom 2000 Qatari and 3000 non Qatari people responded. The authors concluded that there was no significant difference in the prevalence of infertility among Qatari and non Qatari people.

The design of the above study is :

- Crossover
- Cross – sectional
- Case - control
- Concurrent cohort
- Nonconcurrent cohort
6- A group of authors wanted to study the association between schistosomiasis and squamous cell carcinoma of the bladder. The authors chose 100 patients with squamous cell carcinoma and 100 aged and sex matched people with nonspecific cystitis from the database of the hospital. The authors determined the percentage of patients with and without schistosomiasis in both groups and found a statistically higher proportion of schistosomal affection in patients with squamous cell carcinoma.

The design of the above study is:

a- Concurrent cohort

b- Nonconcurrent cohort

c- Case – control study

d- Randomized clinical trial
At 2011, a group of authors checked the files of 2006 and chose 1000 smokers and 1000 aged and sex matched nonsmokers. At 2011 the authors called the 2 groups and examined them for the possibility of lung cancer. The authors found a significantly higher prevalence of lung cancer among smokers.

The design of the above study is:

a- Case - control
b- Concurrent cohort

c- Nonconcurrent cohort
d- Randomized clinical trial
8- A group of authors chose 500 patients with hyperuricaemia and a similar number of age and sex matched persons with normal serum uric acid. The authors followed both groups for the possibility of occurrence of urinary stones. Follow-up included renal ultrasonography every 6 months. After 6 years of follow up the authors demonstrated a statistically significant higher incidence of renal stones in hyperuricaemic group.

The design of the above study is:

a- Randomized clinical trial
b- Case - control
[c- Concurrent cohort study]
d- Nonconcurrent cohort study
A group of 100 patients with lower ureteral stones were randomly assigned to receive doxazosin (α blocker) (50 patients) or placebo (50 patients). Patients were followed up for 4 weeks by plain abdominal x-ray and ultrasonography. Patients receiving α blocker had significantly higher proportion of spontaneous stone passage compared with the placebo group.

The design of the above study is

- Case - control
- Randomized clinical trial
- Concurrent cohort study
- Nonconcurrent cohort study
10- In which of the following study designs masking is suitable to avoid selection bias:

a- Case - control studies

b- Concurrent cohort studies

c- Nonconcurrent cohort studies

d- Randomized clinical trial
Thank you