Total No. of Questions : 10

M.Sc. (Clinical Research)   (Sem.-3)
CLINICAL STUDY DESIGN
Subject Code : UC-MSCR-302-20
M.Code : 79928
Date of Examination: 14-12-2022

Time : 3 Hrs.   **Max. Marks : 70**

INSTRUCTIONS TO CANDIDATES :
1. **SECTION-A is COMPULSORY consisting of TEN questions carrying TWO marks each.**
2. **SECTION-B contains FIVE questions carrying FIVE marks each and students have to attempt any FOUR questions.**
3. **SECTION-C contains FOUR questions carrying TEN marks each and students have to attempt any THREE questions.**

SECTION-A

l. **Answer the following briefly:**

    a. What is matched pair study design?

    b. What is the purpose of blinding?

    c. What are surrogate end points?

    d. Under what conditions clinical trial can be done in paediatric patients.

    e. Under what conditions add on clinical trial designs can be used?

    f. What is cluster randomized trial?

    g. What is the explanation for placebo effects?

    h. What is case report?

    i. What is clinical relevance pyramid for selecting endpoints?

    j. What are the common parameters for deciding inclusion and exclusion criteria?

SECTION-B

2. Explain why sample size in a cross over design is less than parallel design.

3. Explain adaptive randomization.

4. Explain non-inferiority study design.

5. Explain landmark analysis and give its merits and demerits.

6. What is patient attrition. What are the reasons for patient attrition?

SECTION-C

7. What are the objectives, design and analytic methods of cohort studies?

8. Describe the different types of controls used in clinical trials.

9. Describe the clinical trial designs for evaluating Alzheimer Disease drugs.

10. What are ethical considerations for including pregnant women in clinical trials? Under which situations pregnant women can be included in clinical trials.

NOTE : Disclosure of Identity by writing Mobile No. or Marking of passing request on any paper of Answer Sheet will lead to UMC against the Student.