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Diploma in Pharmacy 2nd Year

Pharmacology

Experiment

To study types of pre-clinical experiment: in-vivo, in vitro, ex-vivo, etc.

Aim:

To study types of pre-clinical experiment in-vivo, in vitro, ex-vivo, etc.

Reference :

‘ Dr. P.Mudagal Manjunatha , “Practical Manual of Pharmacology”
Published by Nirali Prakashan, Page no 23 - 26

Theory :

- Animal studies are used in pre-clinical experiments to evaluate a drug's safety, effectiveness, pharmacokinetics, and pharmacodynamics.
- Developing suitable data for deciding the reasonability of being safe to proceed with human trials of the drug is the goal of pre-clinical study.
- Usually, rodents, such as mouse, rats, guinea pigs, hamsters, and rabbits are used in experiments.
- Tests are carried out on larger animals, such as cats, dogs, and monkeys following a positive result.
- Unfavourable compounds are prohibited at each step as the evaluation proceeds.
- Thus, a small number of compounds among thousands achieve the point where its administration to humans is considered.

The safety and efficacy of the drug must be confirmed in pre-clinical studies before being tested in humans. These studies can either be in vitro, ie, studies performed outside the body using cell cultures or in vivo. i.e. studies performed inside human body.

Preclinical studies for in vivo testing only involve animals because this stage comes before human testing to ensure its safety.

Objectives

- ◆ To develop the required data for determining the safety of the process to proceed with human trials of the drug.
- ◆ To determine whether a new drug or medical technology is safe and effective before using it on humans
- ◆ To gather the data to submit to the FDA for IND filing

Types

- 1) **In-vitro** : Cell lines from either human or non human animals are used in in vitro studies, where they are combined with the new drug being developed in a petri dish or test tube.

Advantages

- i. These studies do not have negative effects on animal or human from which the cell cultures were made.
- ii. These studies are repeatable, effective, and producing robust results.
- iii. These studies are relatively cheap to set up and maintain.

Disadvantage

- i. These studies cannot simulate the way a drug would interact with all the chemicals and cell types found in a complex organ.
 - ii. These studies are incapable in estimating the complexity of potential interactions and are examined in isolation because human body is a dynamic environment having various pathways and cells in continuous communication.
- 2) **In-vive** : In comparison to in vitro, in vivo studies are carried out inside a living organism (animals or people as subjects) in preclinical trials.

Advantages

These studies can show the way a drug affects the body as a whole rather than just isolated cells. This enables in vivo studies to more precisely identify potential interactions, which can help them in predicting the safety, toxicity, and efficacy of a drug. This helps scientists in predicting the way potential medications will affect human disease.

Disadvantages

- i. These studies have their own significant drawbacks despite the fact that they address the problem with in vitro studies.
 - ii. These studies raise serious ethical concerns, particularly for preclinical studies where only animal models are permitted. Animal testing has been the subject of a long-running ethical controversy
- 3) **Ex-vivo** : These studies are performed outside a living body, in which living tissues are extracted straight from a living organism rather than being made artificially. The experiment is then carried out instantly in a lab setting with minimal alteration to the organism's natural environment.

Importance of Pre-clinical Trials

- It is used to determine the dose, toxic dose, pharmacological action, etc.
- It is used by the regulatory body to conduct clinical trials.
- It is used to evaluate a drug's safety in animals before applying it to humans from an ethical stance.
- It is used to select the route of administration in humans for clinical trials based on the kinetic profile of drug.

Result :

Types of pre-clinical experiment, in-vivo, in vitro, ex-vivo, etc. were studied.

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