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Development and Creation of Medicines

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Abstract: An article about drug development is the process of bringing a new pharmaceutical product to market. It includes preclinical research in the laboratory before the development of clinical trials.

Keywords: drug reactions, drugs, low doses, drug development.

Introduction

Many currently used drugs were discovered through experiments conducted on animals and humans. However, nowadays many drugs are developed with an eye to a specific disease. First, abnormal changes in the body at the biochemical and cellular level caused by the disease are studied, which makes it possible to further develop chemical compounds that can specifically prevent or correct such abnormal changes (by interacting with certain functional areas of the body - the so-called “sites”) . If a new compound appears promising, its structure is usually modified many times to:

- optimize its ability to target specific organs and tissues selectivity
- maintain connection with relevant organs and tissues affinity
- minimize side effects.

Other factors taken into account include whether the chemical is absorbed through the intestinal wall and how stable it is in body tissues and fluids. The above factors also include the effect of the body on the drug and the effect of the drug on the body.

Literature analysis

Ideally, the drug is

- Highly selective for target sites: its effect on other body systems is negligible or absent, that is, the side effects of the drug are minimal or there are no drugs
- Very strong and effective: low doses can be used even for diseases that are difficult to treat.
- Effective when taken orally (well absorbed from the digestive tract): easy to use.
- Quite stable in body tissues and fluids: thus, ideally one dose per day should be sufficient (short-acting drugs may be preferable for diseases that require only short-term treatment).

Research Methods

During the development of an investigational drug, standard or average doses are determined. However, different people respond differently to medications. The therapeutic response is influenced by many factors, such as age, aging and medications, body weight, genetic

predisposition and the presence of other diseases. General information about the body's possible reactions to the effects of drugs. These factors are necessarily taken into account when the doctor determines the dose for a given patient. Stages of drug development.

(For a summary of the stages of drug development, see the table From Laboratory to Pharmacy Initial Drug Development Once a drug that may be useful in treating a specific disorder has been identified or developed, it is studied in laboratory animals (initial drug development) The initial phase of drug development involves collecting information about how the drug works, how effective it is, and what toxic effects it causes, including possible effects on fertility and the health of the offspring.

At this stage, many drugs are rejected because they are ineffective or too toxic.

If a drug is found to be promising during initial development, the appropriate institutional review board must approve the drug's clinical development program and an Investigational New Drug (IND) application is submitted to the US Food and Drug Administration (FDA). If the FDA approves the application, the drug can be tested in humans (this phase is called "clinical trials").

Clinical researches

This type of research consists of several phases; Only volunteers who have given their written consent are invited to participate in them. Three phases of clinical trials are required for FDA approval:

- Phase 1 evaluates the safety and toxicity of the drug in humans. A small number of healthy young subjects are given the drug at varying doses to determine at what dose the first signs of toxicity appear.
- Phase 2 evaluates the effect that the drug has on the disease/disorder it is directed against and determines the appropriate dosage. Approximately 100 people suffering from a particular disease/disorder are given different doses of the drug to see if it provides any benefit. Just because a drug is effective in animals during initial drug development does not mean it will be effective in humans.
- Phase 3 tests the drug on a much larger (hundreds to thousands of people) population of individuals suffering from a particular type of disease/disorder. The selection of these participants is done in such a way that they are as similar as possible to people who can use this drug in reality. As the drug's effectiveness is further studied, new inherent side effects are noted. Phase 3 studies typically compare a new drug with a known proven drug, a placebo, or both.

RESULTS AND DISCUSSION

In addition to determining the effectiveness of a drug, human studies focus on the types and frequency of side effects and the factors that make patients more likely to experience these side effects (eg, age, gender, presence of comorbid disorders, and use of other medications).

If research has determined that the drug is sufficiently effective and safe, a New Drug Application (NDA) is submitted to the FDA (including data from animal and human studies, the proposed manufacturing process for the drug, instructions for medical use, and label). The FDA then reviews the information provided and decides whether the drug is effective and safe enough to allow it to be sold on the pharmaceutical market. Once approved by the FDA, this drug will become available for use. This process takes up to 10 years in total. On average, of the 4,000 drugs that are studied in laboratories, only about 5 are studied in humans, and only 1 of these 5 drugs is approved and used in medical practice.

Each country has its own approval process, which may differ from the process used in the United States. Just because a drug is approved for use in one country does not mean it is available for use in another country.

Phase 4 (post-registration period)

Once a new drug is approved, phase 4 studies are sometimes conducted. The manufacturer must monitor the drug's use and immediately notify the FDA of any additional, previously undetected side effects. Physicians and pharmacists are encouraged to participate in ongoing monitoring of drug use. This kind of observation is very important because even fairly extensive studies before a drug is released to the market can only detect relatively common side effects (occurring in about one in 1,000 people). Important side effects, which occur in one out of every 10,000 (or more) people with a drug, can only be detected when a large number of people use the drug, that is, after the drug is on the market.

The FDA may revoke approval of a drug if new evidence emerges that the drug causes serious side effects. For example, the dietary drug fenfluramine was withdrawn from the market because some people taking it experienced serious cardiovascular problems.

CONCLUSION

From the circulation of medicinal products - sales, sale and dispensing, including prescription medicinal products to the consumer, use, transfer for destruction, loss and write-off of medicinal products, An article about drug discovery is the process of bringing a new pharmaceutical product to market. It includes preclinical research in the laboratory before the development of clinical trials.

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