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A Review on Pharmacovigilance

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ABSTRACT

Pharmacovigilance defined as "the science and activities relating to the detection, assessment, understanding, monitoring and prevention of adverse effects related to drugs. Aim of Pharmacovigilance is patient safety. This review article contain guidelines such as Good Clinical Practice (GCP) and International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) . In which we study about the drug use, its mechanism of action, adverse effect and how to overcome these effect. and in these we study about the use of a Amphotericine B drug in treatment of MUCORMYCOSIS. Took a look on mechanisam of action side effect, adverse effect And patient interview in that how they get treat when they are suspect of these disease.

Keywords: Pharmacovigilance, Detection, Assessment, Patient Safety.

Introduction:

The role of **pharmacovigilance** is to ensure the safety and efficacy of drugs by monitoring their effects on patients . With help of these study we properly detect the unknown adverse effect and drug interaction . Through these Distribute information about the adverse effect of drugs and drug interactions so that they can occur less frequently . Reevaluation of the risk-benefit balance of medicine, so we can effectively use those drugs for a patient having more benefits and fewer side effects . The main goal of pharmacovigilance is thus to promote the safe and effective use of health products, in particular by providing timely information about the safety of health products to patients, health-care professionals, and the public. Pharmacovigilance is therefore an activity contributing to the protection of patients and maintaining public health

Important of Pharmacovigilance : It is science which deals with complex process of understanding and explaining the nature of ADR occurred in patient taking either oral or or parenteral or interavenous route and overcoming the occur ADR .

Method used in Pharmacovigilance :

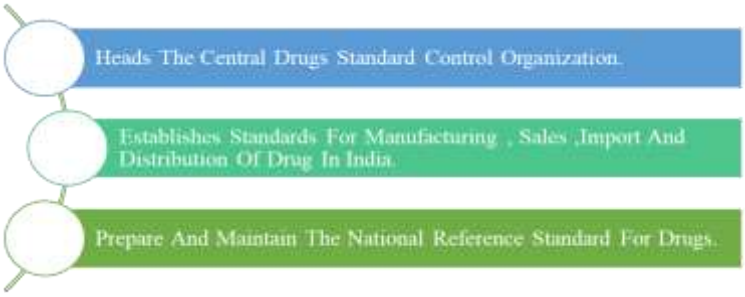
Many researchers developed different methods for assessment of ADR like screening for non drug related causes ,confirmation of reaction by in vivo and in vitro test ,etc and many more are methods are developed .

Pharmacovigilance : Pharmacovigilance has been defined by the world health organisation as “the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problem”.

To Study Pharmacovigilance it performed clinical trials .

Clinical Trials :

Functions of Drug Controller General of India (DCGI)



TYPES OF REGULATORY APPLICATION

1. Investigational new drug (IND)

An Investigator IND is submitted by a physician who both initiates and conducts an investigation, and under whose immediate direction the investigational drug is administered or dispensed. A physician might submit a research IND to propose studying an unapproved drug, or an approved product for a new indication or in a new patient population.

2. New drug application :

is the vehicle in the united states through which drug sponsors formally propose that the FDA approve a new pharmaceutical for sale and marketing.

3. An abbreviated new drug application :

ANDA contains data which is submitted to FDA for the review and potential approval of a generic drug product. Once approved, an applicant may manufacture and market the generic drug product to provide a safe, effective, lower cost alternative to the brand-name drug it references.

Good Clinical Practices

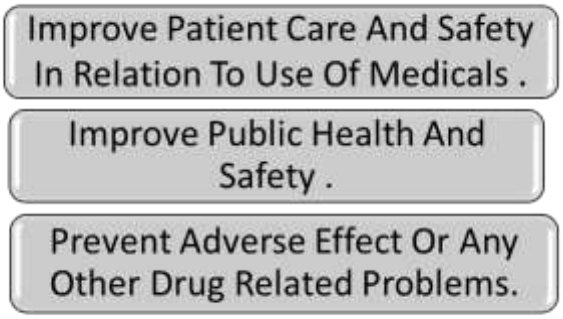
Scope of ICH –Good Clinical Practices

It gives methodologies and procedures to be used to monitor and ensure the safety, quality and efficacy of medicines intended to treat humans.

Protocol Designing For Clinical Trials

Process of clinical trial application in pharmacovigilance

Objectives of Pharmacovigilance

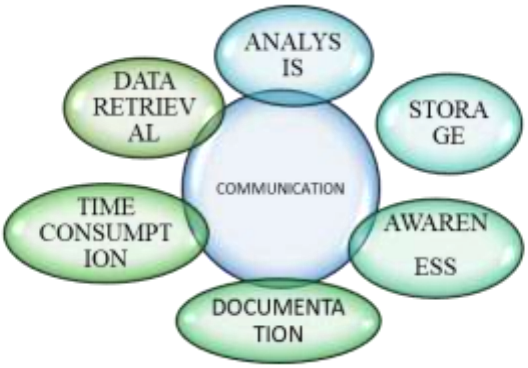


Types and Components of Pharmacovigilance

Constitution and objectives of pharmacovigilance program of India

- The national pharmacovigilance program is coordinated at central drug standard control organization office .
- Aims
- Monitoring adrs.
- Review psurs.
- Recomondations regarding label, amendements and withdrawal .
- Provides information through bulleteins , drug alerts and seminars .

Function of National Adverse Drug Monitoring Centers



List of National Adverse Drug Monitoring Centers and Their Functions

Functions of the who programme for international drug monitoring include

- Identification and analysis of new adverse reaction signals from case report
- Information exchange between WHO and National Centres mainly through an Email .
- Publication of periodical Newsletters , Guidwlines and Books in pharmacovigilance and risk management area.
- Providing Training and Consultancy Support to National Centres and Countries

International Conference on Harmonization E2e Guidelines

Safety specification can include

1. Identified risks .
2. Important potential risk .
3. Important missing information.

Non Clinical safety specification

- Non clinical safety findings that have not been adequately addressed by clinical data .For example
- Toxicity
- General pharmacology
- Drug interaction

Other toxicity related information and data.

- Limitation of the human safety database
- Population not studied in the pre – approval phase
- Adverse drug reaction
- identified and potential interactions , including food -drug and drug-drug interaction
- Epidermology.

Identification and evaluation of risk including drug -drug interaction and drug -food interaction

- What is the time course of the interaction ?
- What is class of the given drug ?
- Is the interaction clinically significant ?

Design and conduct of observation studies

An **observational study** is a form of qualitative research in which the researcher observes participants' behaviour. There are different types of observational studies, such as controlled, naturalistic, and participant studies.

This second edition of Design of Observational Studies is both an introduction to statistical inference in observational studies and a detailed discussion of the principles that guide the design of observational studies.

Selected Class of Drug :

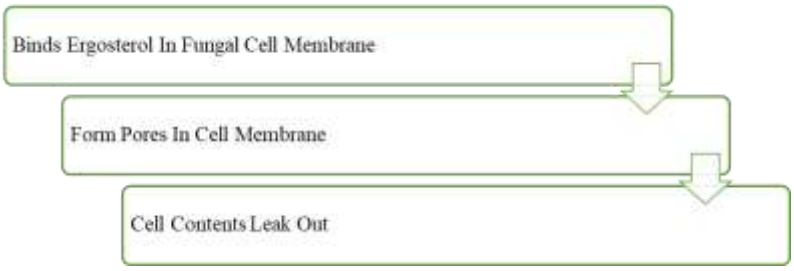
- Antifungal Class
- Drug name is Amphotericine – B .
- Antifungal Drug Define
- The drug which are used to treat fungal pathogen / infection that drug called as antifungal drug .

Eg : Amphotericine B .

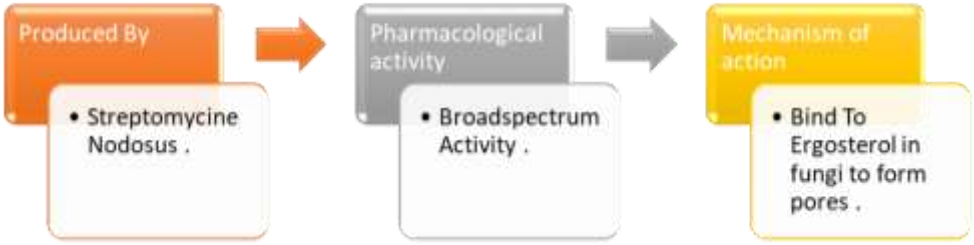
Amphotericine B

- Amphotericin B is for serious, life-threatening fungal infections. It is not for use in treating a minor fungal infection .
- It used to treat infection like mucormycosis fungal infection .
- Amphotericin B given to patient by oral or by intravenous route .
- Some available medicines are
- Ampholip
- Amphomul
- Amfy v
- Fungizone , etc .

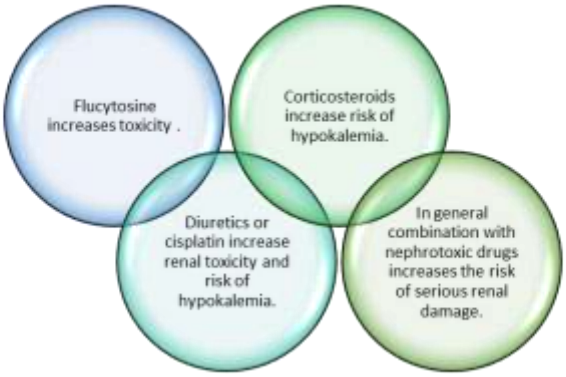
Profiling of Selected Drug Class Mechanism of action (amphotericin –b)



Pharmacological Effect

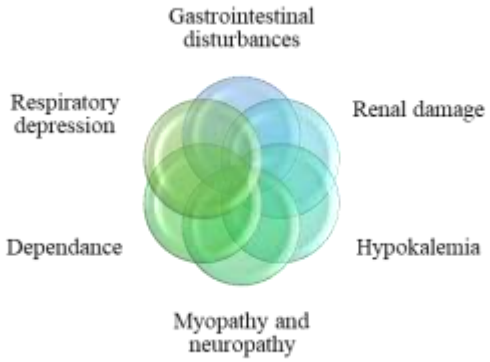


Drug Interaction



Contraindication and Side Effects

Side effects



Conclusion

It observes that because of antifungal property Amphotericine B will be very useful in the treatment of Mucormycosis .

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