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Review Article

Pharmacology Section

Ethical and Legal Aspects of Conducting Clinical Trials in Alcohol Withdrawal Syndrome

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ABSTRACT

Alcohol Withdrawal Syndrome (AWS) is a condition where the patients will be mentally unstable initially and where later, with therapy, they gradually return to normalcy. As AWS comprises two stages; a mentally unstable state and a normal state of mind, the ethical and legal issues behind recruitment of these subjects become a little ambiguous in a clinical trial. This study was taken up to clarify the uncertainty regarding the biphasic states of minds (i.e. unstable mind and sound mind) of the subjects who were involved in a clinical trial done on AWS. Law and ethics regarding the clinical trials which involve psychiatric subjects need to be strengthened and amended from time to time, in order to protect the interests of both patients and physicians.

Keywords: Ethics, Law, Clinical trials, Alcohol withdrawal syndrome, Off label use

INTRODUCTION

A clinical trial involves human subjects when it is done to test a new intervention. The rules and regulations which are followed in a study vary from nation to nation and from disease to disease. The ethical and legal considerations would be more or less similar to those of most of the clinical trials, but when it comes to a clinical trial which involves mentally unstable subjects, the law and ethics undergo certain changes from the regular mode, as it is a different entity and as there will always be questions and enquires when the study involves mentally unstable patients. The rules and regulations will also vary accordingly [1]. Alcohol Withdrawal Syndrome (AWS) is a condition where the patients will be mentally unstable initially and where later, with therapy, they gradually return to normalcy. Hence, there exists some uncertainty in enrolment and management of these subjects with variable mental stabilities. This vagueness also involves risks, as it interlinks both ethical and legal issues in recruitment of mentally unstable subjects who return to their normal states of mind in both clinical practice and in clinical trials [2]. This analytical study was taken up to clarify the uncertainty regarding the biphasic states of minds (i.e. unstable mind and sound mind) of the subjects who were involved in a clinical trial and the variations and regulations in ethics and law like:

1. Consideration of unstable mental status when a clinical trial which was being done on AWS was being approved.

2. Comparing a trial drug with a placebo and comparing a trial drug with a standard drug: ethical and legal aspects?

3. Off label use of drugs: ethical and legal implications?

4. Whether a patient with AWS who was undergoing treatment in a clinical trial could enter into a contract. If yes, in what stage of the therapy?

5. Aversive therapy: Giving medicine in disguise in food/drinks to the patients by his/her family members- ethical and legal aspects.

1. Consideration of unstable mental status when a clinical trial being done on AWS was being approved.

Analysis of the trial, considering the subjects as psychiatric patients in the primary stages of therapy: In the earlier stages of the therapy, the withdrawal symptoms could be manifested in the subjects. These symptoms could burst out as seizures, hallucinations, delusions, depression, anxiety, and agitation and so on. In such situations, the subjects would have unbalanced psyches that had to be considered as mentally unstable conditions and hence, they had to be viewed in a different aspect:

a) Institutional ethical committee (IEC) should ensure that the protocol and methodology are equipped with the rules and regulations of the Mental Health Act, till the subjects returns to normalcy, which has to be ascertained by the principal investigator.

b) Other than the emergency and intensive care facilities which are available at the trial site, it is also essential that the subjects be placed in a separate ward and that they do not mingle with the other psychiatric patients.

Mental Health Act, 1987

Mental Health Act was drafted by parliament in 1987, but it came into effect in all the states and union territories of India in April 1993. This act replaces the Indian Lunacy Act of 1912, which had earlier replaced the Indian Lunatic Asylum Act of 1858 [3,4].

Aim of the act

"To consolidate and amend the law which relates to the treatment and care of mentally ill persons and to make a better provision with respect to their property and affairs and for matters which are connected therewith or are incidental thereto."

Salient features of the act

Mental Health Act is divided into 10 chapters which consist of 98 sections.

Chapter I: Deals with preliminaries of the act, definitions and it provides for change of offensive terminologies which are used in Indian Lunacy Act, 1912.

Chapter II: Deals with the procedures for establishment of mental health authorities at central and state levels.

Chapter III: It lays down the guidelines for establishment and maintenance of psychiatric hospitals and nursing homes. There is a provision for licensing authorities to process applications for license, which have to be renewed every five years.

Chapter IV: It deals with the procedures of admissions and detentions of mentally ill patients in psychiatric hospitals.

Chapter V: It deals with the inspection, discharge, leaves of absence and removal of mentally ill persons.

Chapter VI: It deals with the judicial inquisition regarding alleged mentally ill persons who possess property and its management.

Chapter VII: It deals with the maintenance of mentally ill persons in a psychiatric hospital or in psychiatric nursing homes.

Chapter VIII: It deals with the protection of human rights of mentally ill persons.

Chapter IX: It deals with the penalties and procedures for infringement of guidelines of the act.

Chapter X: It deals with miscellaneous matters which are not covered in other chapters of the act.

The chapters IV to X are crucial, which explain the right ways by which mentally ill subjects should be enrolled and discharged from psychiatric institutions. Admissions of alcoholics are done in two forms, 1. Patients are brought by the attendees when they already have the withdrawal symptoms and 2. Patients voluntarily ask for the therapy in order to stop the habit. The patients with withdrawal symptoms, who are brought to the hospital by their attendees, will be in a state of delusion and sometimes in a hallucinating state. They regain their normal health by 2-4 days after the initiation of withdrawal therapy [5].

Chapter IV: Chapter IV of Mental Health Act includes three routes by which a mentally ill patient can be admitted into a mental health care facility.

The first element is admissions of mentally ill patients: a) Made on voluntary basis: Any person who is a major (above 18 years of age) can make a request for an admission into a health facility, voluntarily to the medical officer who is in-charge of admissions of such patients into the hospital/psychiatric institution.

b) Made on basis of requisitions made by the guardians/legal representatives: On making such requisitions, the medical officer in-charge should conduct detailed enquiries and examine the patients and only after that, he should be assured of patients mental illnesses and admit them into the health facility. This procedure should be completed within 24 hours, on receipt of applications for admissions of patients to wards.

c) Made under special circumstances: When a mentally ill patient cannot express his/her willingness or give consent for admission due to his/her mental incapacity, the same may be requested by his/her guardians/legal representatives, which should be accompanied by at least two medical certificates given by two physicians in a prescribed format to the medical officer in-charge.

Chapter V: Discharge of mentally ill persons: Medical officer in-charge can direct the discharge of a patient by issuing a written summary of the treatment, if he feels that the subject is dischargeable. Patients who are admitted on the basis of applications which are made under the rules of the act, can be discharged only when the concerned persons make applications for their discharges. This however, requires recommendations from two practising physicians. Any patient who feels that he/she has recovered from his/her mental illness may make an application for his/her discharge.

Analysis of the trial, considering the subjects as non-psychiatric patients in the later stages of the therapy: In the later stages of the withdrawal therapy, the subjects return to normalcy, where the rules and regulations of the Mental Health Act are not applicable. Hence, the subjects should be considered as normal and their ethical aspects should be assessed in the respective prospect [6]. Unnless and until the patient is deemed to be mentally fit, the rules and regulations of the Mental Act apply to all the mentally ill patients. Hence, the procedures which are enlisted in the act should be followed for admissions or discharges of such patients, both in clinical practice and in clinical trials.

2. Comparing a trial drug with a placebo and comparing a trial drug with a standard drug: ethical and legal aspects?

Placebos which are also called as sugar pills are pharmacologically inert substances which are used to mimic/disguise an effective treatment, which does not possess any therapeutic advantage and still can produce an effect which might be positive or negative, because of the psychological impression that it makes on the subject. Two types of placebo substances are used: 1. Active placebo and 2. Inactive placebo. Active place bosare inert substances which can mimic the side effects of the experimental drug, whereas inactive placebos don't have this quality [7].

The debate continues about the feasibility and practical applicability of placebos in experimental research.

ICMR guidelines: The ICMR guidelines on the use of placebos in clinical trials:

A randomized controlled trial (RCT) is the best known method which can be used to bring out unbiased results in a clinical trial, which are ethically acceptable, if the investigational drug is compared with the standard drug. The ethical dilemma presents when the trial drug is compared with the placebo, wherein appropriate scientific and methodological reasonings should be provided. ICMR guidelines uphold Declaration of Helsinki principles of using a standard therapy in the control arm whenever it is available. Guidelines allow the use of placebos under following circumstances: Self limited disease. Where no proven prophylactic, diagnostic or therapeutic methods exist [8].

Placebo-controlled trials are not an essential requirement for the Drugs Controller General of India (DCGI), for him/her grant an approval for drug marketing. However, the DCGI does not ban the use of placebo-controlled trials.

Advantages of placebo controlled studies

1. **Fewer subjects, Cost minimization, Shorter duration and Safety:** Since the differences in response rates are likely to be greater between a new, effective medication and a placebo, as opposed to a standard effective drug, studies which use placebos have greater statistical power and they can also recruit smaller numbers of subjects. Placebo controlled studies not only diminish the costs and durations of studies, but they also reduce the number of subjects who will be exposed to potential adverse effects of the new medication. If placebo-controlled trials are more efficient, new therapies will be made available more quickly at lesser costs.

2. **Better screening of the drug molecules:** If the trial drug is proven to have the same efficacy as that of the placebo, then the drug molecule can be withdrawn from the study, which not only reduces the unwanted monetary expenditure, time which is invested on the study, but it also prevents the further promotion of the clinical trial to higher stages. Rejection and selection of newer drug molecules and their potentials can be assessed without compromising on the safety of the subjects.

3. **Tests the competency of the trial drug:** In most of the cases which involve psychiatric clinical trials, the placebo arm shows equal effectiveness as compared to that of the investigational drug. thus providing a demanding test for the trial drugs. It further paves way for producing better drug molecules.

Disadvantages of the placebo –controlled clinical trials

1. **There is more harm than benefit:** Patient volunteers who are on placebo arms of clinical trials which test the efficacy of drugs for the treatment of various health disorders, may experience worsening of the symptoms, which can even result in life threatening complications.

2. **Deprivation of the needful treatment**: Subjects who receive placebos may be deprived of the needful treatment when the trial drug produces effective results for a particular health condition and the subjects in trial drug arm get the benefits early.

3. **Misuse of placebo controlled trials:** Placebo controlled trials may be misused by the drug manufacturers. Comparing a low efficacious trial drug with a placebo which will eventually churn out a better therapeutic advantage than the placebo arm, by which a company can gain approval for the marketing of the drug, which can lead to accumulation of non-efficacious medications in the market [9].

4. **Increased drop-out rates:** Subjects who are on placebos can experience exaggerations of their disease states and symptoms, which can result in patients withdrawing their consents and hence, placebo controlled trials may have increased dropout rates, which can prolong the trials.

Liability for Medical Negligence: Claims of medical malpractices are usually brought under the tort of negligence; medical negligence covers all the therapeutic modalities, clinical trials, regular clinical practices, trial drugs, standard drugs and any interventions which are provided to patients. Medical negligence can come under both civil and criminal liabilities. In clinical trials which involve subjects who are treated with placebos, when the placebo use is not justified scientifically and ethically, it may be brought to trial in court as gross medical negligence, as placebo therapy is considered as good as giving no treatment [10].

Duty: In order to have a legal proceeding against the investigator / physician, the following elements have to be proved. For the alleged medical negligence to be considered, the research participants who are harmed must first prove that the physician/investigator owed them a duty of care. That the placebo therapy was administered to the patients though the standard therapy was available.

That the placebo therapy was the chief cause of the injury or the exaggeration of the disease. The use of placebo in clinical trials as a comparator agent with the drug, has its advantages and disadvantages. The investigators of clinical trials, which involve placebo controlled trials, need to be aware of the rights of the patients and more importantly, about the regulations which govern clinical trials, especially in placebo trials done on psychiatric subjects.

3. Off-label use of drugs: ethical and legal implications?

When a drug is used for therapeutic interventions other than its approved indications, it is called as an off label use of a drug. The drug may be approved by the regulatory authority for a particular condition, but when the same drug has beneficial use in other conditions, it can be used by the physicians to treat those conditions which do not need an approval from the regulatory bodies. This also includes prescribing the drug outside the approved dose and frequency chosen for an approved or an unapproved condition [11].

Regulations allow the physicians to use approved drugs for unapproved indications according to their will, if it justifies benefits to the patients. No particular rules/regulations have been established to oversee off label drug use, both in clinical practice and in investigations.

Ethical issues: While using a drug for off label use, investigator/ physician may not explain the methodology of the study to the subject/patient and as the drug will be approved for another indication, this might go against the fundamental ethics of his/her informed consent. Patient may not be educated about the risks and benefits of the off label drug use, which takes away the autonomy of the subject to know as to what therapy he/she is getting. As off label drug use is a different entity during the clinical trials, which consists of off label drugs, many of the ethical norms may not be followed, as dilemma exists on the off label drug use in clinical trials.

Legal Issues: Drug regulation provides complete freedom to the treating physicians to use medicines for off label use, as physicians are entitled to choose right drug for a patient. Off label use of a drug is permitted to be tailored and individualized according to the necessity of the patient. This allows the physician to conduct his/her clinical practice with flexibility. Though physician has complete freedom in treating a patient, sometimes, a proof would be required to justify decision which he/she made on off label use, although without justification, it can be carried out. Justification will be easy when there are already some case reports/articles which have cited the intervention.

Off-Label Use and Clinical Experimentation

The disparity between the off label drug use in clinical practice and clinical experimentation still prevails and thus, to ensure clarity and equality in off label drug use, basic rules and regulations have to be established on off label drug use by the regulatory authorities, to protect patients' rights in human experiments.

The disparity between clinical use and experimental use of drugs is mainly caused by: Reluctance of regulatory bodies in interfering with the physicians' diagnostic, therapeutic and prophylactic measures, as it is righteous for physicians to choose the best treatment and to tailor the drugs according to the needs of their patients. Any rules and regulations related to this matter may unsettle the physicians' choices and flexibilities connected to treatments of their patients.

On the other hand, there is a need for protecting patients by ensuring safety and efficacy of the drugs which are in the market and preventing their misuse, which is only possible by imposing rules and regulations [12].

According to the regulatory authorities, once a drug enters the market, a physician is lawfully entitled to utilize the drug or the device and to tailor it, depending on the need of his/her patients, without getting any prior permission or approval from regulatory bodies. The off label use of medicines does not come under the laws and regulations of clinical trials per se. Dichotomy in the laws and ethics which regulate off-label drug use for the manufacturers and the doctors, fails to sufficiently protect the patient. It is hence, essential to clearly demarcate the off label drug use in clinical practice and clinical research, and to lawfully/ethically regulate the off label drug use in human experiments.The establishment of stringent laws and regulations in off label drug use in human experiments ensures safety and protects the patients' rights in clinical research. This should also ensure complete freedom for the physicians who treat their patients in clinical practice settings.

4. Can a patient with AWS who undergoes treatment/ a clinical trial enter into a contract? If yes, in what stage of the therapy?

Contract: An agreement or a promise which is enforceable by law is called as a contract. An offer which is made by one person, when it is accepted by another person, becomes an agreement. An agreement is the sum of offer and acceptance. The law which relates to contracts has been included in the Indian Contract Act, 1872.

Capacity of parties-competency: A person is entitled to enter into a contract if he/she.

a) Is a major.

b) Has a sound mind.

c) Has not been disqualified from contracting under any law.

Free and genuine consents of the parties: During the signing of the agreement by both the parties, there should be no use of force/ influence on the parties and the parties should be in terms and free minds.

Signing of a contract by mentally unstable persons: The term, 'mentally unstable' involves different types of psychiatric and medical conditions, wherein the affected person suffers from hampered thinking, processing and judgemental capabilities. The law takes into consideration the condition and the mental capacity of the person, while deciding on the judgements in court. The debate is still going on about certain points of these issues. Understanding of the law by mentally disabled persons who sign a contract is an elaborate verbose. Some important critical points have been discussed below.

What does the law say? What if it is signed?

A contract is said to be void, if one of the parties, at the time of making the agreement, was incapacitated in mind, with sub optimal

or absence of cognitive properties such as thinking, understanding and was incapable of judging what he/she was doing, due to insanity or any other medical condition. The contract which a mentally unstable person has entered into, can be valid in the court of law, provided the other party can prove that he/she did not know about the person`s unstable mind/psychiatric condition, and such contracts are considered as fair contracts. The insane condition which develops after a person has entered into a contract, does not make it an invalid contract, but it may be considered as void if the affected mental condition completely disables the person from providing the promised service. The mentally unstable condition does not imply that the contract is void, unless the agreement is taken to the court for dissolution, based on the mental condition of one of the parties.

A person, with a psychiatric/medical condition, who usually has an unstable mind, but occasionally has a sound mind, who doesn't have any signs and symptoms of mental disability (this period or an interval which is called as lucid interval), may make a contract, provided his/her mental soundness is demonstrated and certified by experts. What if the person is on therapy for the same; can he/she enter into a contract?

If yes, at what stage? Law says that a person who is under therapy for a altered mental condition may enter into a contract if the person is certified by a group of experts and treating physicians, that the person`s capabilities were adequate and that his/her mental state was optimal for processing of thought and judgement [13].

In what stage of therapy can a patient be allowed to enter into a contract?

Different medical conditions present as different forms of mental illnesses; conditions such as uncomplicated depression, irritable states, and excited states do not account for medical illnesses. Psychiatric conditions differ in their treatment modalities and durations and hence, the stage where a patient becomes eligible for signing an agreement varies accordingly. Some medical conditions may have gross variations in their presentations, which may alternately present with episodes of mental illnesses and normal states; hence a group of experts which consists of both medical and legal faculties, is necessary to analyze the situation of the patient. It vastly depends on the certification given by the physician about the mental state of the patient and as to who should decide on the mental fitness, prior to signing of the agreement, irrespective of whether the patient is undergoing the therapy or not [14].

Alcohol, which acts as a stimulant in smaller doses, can cause depression and an altered mental state if it is given in larger doses, which subdues the judgemental capacities of the person. Any person who is under the influence of alcohol, if he/she enters into a contract, the contract becomes void, unless it is proved otherwise. In AWS, when a patient is admitted to a medical setting, most of the times, he/she will have disorientation, altered sensorium, hallucinations, which hinder the thought processes and judgemental capacities of the person, which amounts to mental unstableness; hence, it is clear that the person cannot enter into a contract at this stage.When treatment for AWS is started, depending upon the severity of the condition, the recovery may vary for different persons (for them to return to their normal senses), it being normally about 5-6 days.. Even at these stages, the person`s mental stability has to be assessed before any contracts are undertaken. After about 5-6 days of therapy, if the person returns to normalcy, the physician can examine the patient and if he/she is certified to be medically and mentally fit, he/she can enter into a contract.

5. Aversive therapy: giving medicine in disguise in food/drinks to the patient by family members- ethical and legal aspects?

Aversive therapy is a mode of treatment, wherein a drug is used to prevent a person from consuming alcohol. If a patient who is on aversive therapy consumes alcohol, the person experiences noxious and intolerable symptoms like dizziness, vomiting, headache, blurring of vision and others, which disinclines the person towards the consumption of alcohol. The drug which is most commonly used for aversive therapy in AWS is disulfiram.

Administration of drugs by hiding them in foods and drinks, can be allowed in the following conditions:

1. In patients with mental illnesses with impaired judgemental capacities, who are unwilling to take any sort of medications when they are given to them.

2. In paediatric age group, for those who refuse to take medicines, citing bad taste and show aversive reactions on sight of medicines.

These methods of drug administration are righteous and lawful only when the medicines are a necessity and when they are administered in the best interests of the patients [15].

Other conditions in which medicines can be given in disguise in food and drinks, which is ethically suitable:

1. If the therapy is in the best interests of the patients.

2. If the medication is a necessity for survival of the patient/an emergency situation.

3. If it is of grave importance for the improvement of quality of life and general health of the patient.

This has to be done only on physician`s advice, if the patient is admitted in a hospital setting. The reasons for allowing the practice of hiding medicines in patient`s food and drinks should be clearly mentioned on the case sheet by the physician.

Until and unless it is allowed or accepted, no medication should be given to a patient who clearly rejects the treatment which is offered to him/her, irrespective of his/her judgemental/mental capacities, but a patient can give his/her consent to receive medications in food or drinks [16].

Law: It amounts to an unlawful act which invites civil/criminal suits, if a patient is administered the drug by hiding/ it in food and drinks. Even though the treatment is planned for the benefit of the patient, it should be properly explained to the patient prior to the therapy. In case of mentally disabled patients, consents should be obtained from their guardians/legal representatives. In AWS: In AWS, if aversive therapy given to the patient without his/her knowledge and if the patient unknowingly indulges in alcohol, then the resulting aversive symptoms which the person is not aware of, may result in devastating consequences and there are instances where giving aversive therapy in AWS has resulted in deaths. On the other hand, the aversive therapy which is administered by disguising the medication will eventually benefit the patients and prevent the health hazards which result from alcoholism. The debate continues over the ethical and legal implications of hiding medicines in cases of AWS, as both advantages and disadvantages are equally weighed.

Suggestions

With regards to giving aversive therapy to AWS patients to curb alcoholism, it is better to follow the below steps:

The aversive therapy should be explained to the patient and also, to his/her relatives in detail; also regarding the health benefits and health hazards of the therapy. Counselling the patients and their relatives properly will ensure giving a non problematic therapy for the patients, with a considerable reduction in the risks, both for the patients and the physicians.

If the patient is admitted and is not in a position to obey commands or rejecting the therapy actively or passively, then the physician can decide and allow the medications to be given, mixed with food and drinks, and reasons for the same should be mentioned in detail in the case sheet. It is also advisable to get written consents from the patients'guardians/legal representatives regarding the same.

CONCLUSION

Laws and ethics regarding the clinical trials which involve psychiatric subjects need to be strengthened and amended from time to time, in order to protect the interests of both patients and physicians.

Further Reading

1. World Medical Association Declaration of Helsinki http://www.wma.net/en/30publications/10policies/b3/17c.pdf

2. The Mental Health Act, 1987: http://nhrc.nic.in/Publications/Disability/annexure3.html

3. Bulletin of the World Health Organization: Clinical trials in India http://www.who.int/bulletin/volumes/86/8/08-010808/en/index.html

4. Concealment of medications in food and drinks, http://www.ukppg.org.uk/tablets-in-food.html

5. For further information on medical and research ethics, kindly refer to Indian Journal of Medical Ethics, http://www.issuesinmedicalethics.org/

6. Good Clinical Practices for Clinical Research in India, http://cdsco.nic.in/html/GCP.htm.

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