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Research Article

Format for Standard Protocols

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ABSTRACT

This protocol outlines the methodology and procedures for a prospective clinical research study aimed at [briefly describe the main objective or hypothesis]. The study is designed to [outline the primary goals, such as evaluating the effectiveness, safety, or comparative aspects of an intervention]. The research will be conducted at [name of the institution or study sites], involving [briefly describe the target population, inclusion/exclusion criteria]. The protocol provides a detailed description of the study design, including the randomization process, blinding procedures, and the data collection methods. Ethical considerations, such as informed consent procedures and protection of participant confidentiality, are thoroughly addressed in accordance with [relevant ethical guidelines and regulations]. Key assessments, endpoints, and statistical analyses are specified to ensure the robustness and reliability of the study findings. The protocol also outlines strategies for participant recruitment, retention, and monitoring to maintain the integrity of the research. Furthermore, the document details the responsibilities of the research team, including investigators, coordinators, and data analysts. Quality control measures and risk management strategies are integrated to enhance the overall validity and reliability of the study outcomes. This protocol serves as a comprehensive guide for both the research team and regulatory authorities, ensuring adherence to ethical standards and scientific rigor throughout the study duration. The findings of this research aim to contribute valuable insights to the field of [specific field of medicine or healthcare], potentially influencing clinical practice and improving patient outcomes.

INTRODUCTION

Title of the Study:

Ex:- Randomized triple/double/single blind/open clinical trial of Non-alcoholic,

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Non-obese and Non-Diabetic FLD Grade – I & II [Simple Fatty Liver Disease Grade I & II (Steatosis)] with Unani Coded drug ---------- in comparison with ----------

1. Literature of the Disease, Standard drug and preliminary data of the drug under trial:

This includes the spectrum of the disease, clinical features (including primary, secondary and tertiary) and their characteristics, Full details of the standard drug(s) with which the new drug is going to be verified / compared. Preliminary data (data from previous phases) of the drug under trial.

2. Background of the study:

The need of the study in present scenario, (the pressing need of the study in terms of its impact on public health procedures, its incidence, prevalence, the national priority of the study, the hypothesis and objective(s) of the study.)

3. Specific objectives:

Every study will be started with some objectives, the primary and the secondary objectives. The primary objective will be to w establish the efficacy while the secondary includes side effects, toxicity, maintenance of the effects on ceasing the intervention, etc.,

4. Patient Selection Criteria:

A set of diagnostic, criteria in order, to select the patients for the trial. It is very essential that the selection criteria (yardsticks) should be stated clearly and unambiguously, so that the comparability of the findings is preserved for reference of the future trial operators. The patients should represent parent population of the study for effective and reliable findings and decisions.

6.Treatment schedule:

The form, size, shape, dose of the drug, route, frequency, combination, and duration of administration. Manufacture, coding and packing of the drugs etc.,

7.Method of Patient evaluation:

Classification of illness, procedures of patient evaluation in terms of Clinical and Laboratory investigations. Classification of symptoms on cause and effect basis, precautions adopted to measure the accuracy, method of investigations, equipment to be used while recording the subjective and objective answers, etc.,

8. Trial design:

Whether it is parallel group, matching pair, factorial, cross over, sequential, adaptive, open, single, double or triple blind on the basis of the question being asked and the nature of the disease.

9. Registration & Randomization of Patients:

Parting the patient with full details of the experiment in terms of its purpose, length of the study, the probable outcomes, the degree of patients involvement, etc.,. On registration the patient will be assigned to treatment groups on randomization methods as demanded by the study design. Ex: Simple random, systematic randomization. Stratified randomization, random blocks etc.,

10.Patients consent:

The patients those willing to take part in study, he/she should give a written document (Consent) for his/her involvement in the study, his/her co-operation through out the study, acceptance hospitalization if required etc.,

11.Required Size of the Study:

It is mandatory on the part of the Investigator to specify the standardized difference which is clinically acceptable between the two treatment groups. The power of the study to test the above difference The size of the study (level of significance)

12.Monitoring of trial progress:

On commencement of the experiment in single / multi center the committee nominated by the investigator (consists of non participants in the study with at least one statistician) will monitor the progress of the study for its smooth completions.

13.Forms and data handling:

On the basis of the objectives and protocols of the study specific formats to record the data have to

designed such that only relevant information can be recorded. Care should be exercised to exclude the information which is not relevant with the study. Separate formats can be designed for follow-up to preserve blindness of the case sheet. Also is very important to specify whether open or closed type of questionnaire. Computation mode (manual, computer, packages to be used if opted for computers.)

14.Protocol deviations:

Steps have to be adequately addressed in protocols to curb the deviation or violation of the trial procedure, because the deviations and violations in protocols during execution of the experiment will lead to in-appropriate and insensible analysis, findings and conclusions. In case any violation the methods to be adopted for rectification. Withdrawal of the patient due to un-avoidable reasons.

15.Plans for Statistical Analysis:

It is mandatory to specify while drafting the protocols pertaining to the place, mode of computations, packages to be used, type of analysis for both subjective and objective type of data, and their presentation and interpretation, on completion of the study

Note: - the protocol is a document that should be adhered strictly in its toto. It should be treated as sacrosanct of the study.

Points for discussion

1. **Standard drug**
2. **Literature of the Standard drug**
3. **Patient populatio**
4. **Treatment Schedule**
5. **Base line considerations in case of MM therapy**
6. **Washout period in case of Cross over studies**
7. **Standardized difference between treatment procedures (Expected and clinically acceptable difference**
8. **Power of the Study**
9. **Size of the Study**
10. **Case Record format (Closed or Open)**
11. **Blinding of the format**
12. **Measure of Outcome**

CONCLUSION

In conclusion, this meticulously designed clinical research protocol establishes a robust framework for the investigation into [main objective or hypothesis]. The comprehensive methodology outlined herein reflects a commitment to scientific rigor, ethical integrity, and the generation of meaningful data.

The careful consideration of study design elements, including randomization, blinding, and rigorous data collection procedures, ensures the reliability and validity of the outcomes. By addressing ethical considerations in accordance with [relevant ethical guidelines and regulations], we affirm our commitment to participant welfare, privacy, and informed decision-making.

The protocol provides a clear roadmap for the research team, detailing their roles, responsibilities, and expectations throughout the study. Provisions for participant recruitment, retention, and monitoring underscore our dedication to maintaining the highest standards of quality and adherence to the research plan.

As we embark on this clinical research endeavor, we anticipate that the outcomes will not only contribute to the scientific body of knowledge in [specific field of medicine or healthcare] but also hold the potential to inform clinical practice and improve patient care. By adhering to the principles outlined in this protocol, we aim to uphold the highest standards of research conduct and deliver findings that have a meaningful impact on healthcare practices.

This protocol stands as a testament to our commitment to advancing knowledge, improving patient outcomes, and maintaining the highest standards of scientific and ethical conduct throughout the course of this study.

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