"Azadirachta Indica – A Double-Blind Randomized Placebo- Controlled Parallel Study Homoeopathic Pathogenetic Trial in accordance to the protocol given by Central Council of Research in Homeopathy."

[1]Dr. Anand Pal Singh Kushwah, [2]Dr. Manisha P. Gajendragadkar, [3]Dr.Komalba Zala

[1]Ph.D. Scholar, Department of Homeopathic Pharmacy, Bharati Vidyapeeth (Deemed to be University) Homoeopathic Medical College, Pune.
[2] Ph. D. Guide, Professor , Department of Homeopathic Pharmacy, Bharati Vidyapeeth (Deemed to be University) Homoeopathic Medical College, Pune.
[3] Assistant Professor , Department of Obstetrics & Gynaecology, Kamdar Homoeopathic Medical College and Research Centre ,Rajkot.
[1] Email - Anandkushwah191@gmail.com,
Contact Number:7974840780

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RDBPC,epidemiologic,gold standard,HPT.

ABSTRACT

Studies are ranked according to the quality of the evidence they can offer. In epidemiologic research, randomized double blind placebo control (RDBPC) trials are regarded as the "gold standard." Additionally, the same is covered in detail in this paper using an actual journal article as an example, using this study design to respond to "Does a once daily dose of Valacyclovir reduce the risk of transmission of genital herpes in a susceptible partner?" is the research question. The most compelling research design is still RDBPC studies, which use random assignment of the intervention to remove the impact of unknown or immeasurable confounding variables that could otherwise result in a skewed and inaccurate estimation of the treatment effect. I hope this is helpful. to novice researchers in order to comprehend causal hierarchy when assessing epidemiologic literature critically.

Background: "Azadirachta Indica – A Double-Blind Randomized Placebo-Controlled Parallel Study Homoeopathic Pathogenetic Trial in accordance e to the protocol given by the Central Council of Research in Homeopathy.

1. INTRODUCTION

Homeopathic Pathogenetic Preliminary is a particular technique utilized in the homeopathic arrangement of medication to figure out the viability of another medication. It is finished by giving the new medication to a sound person called a "Prover" portion by portion to figure out the signs and side effects created by the Prover. It is a technique for recording the whole signs and side effects of another medication. The medication is to be demonstrated and won't have any demonstrated records of signs and side effects. Azadirachta Indica consumes portions of the plant for the vast majority restorative purposes like Anthelmintic, Against ulcer, Bronchitis, Asthma, Wound recuperating, Hostile to bacterial and different applications.

Causal Hierarchy: To ascertain if an exposure is directly accountable for a certain outcome, epidemiologists assess the available data. Research comes next. a ranking according to the caliber of the proof they are able to offer. The "Randomized Controlled Trial" (RCT) is the most robust study. In order to address the research question, "Does a once daily dose of Valacyclovir reduce the risk of transmission of genital herpes in susceptible partner?" the same is covered in detail in this paper using an example of an actual journal article that uses this study design. The research Heterosexual couples from 96 study sites who tested negative for HSV-2 infection were the population under investigation.[1] **The crucial terms are:**

Clinical studies:

Clinical trials are prospective investigations in which participants are given "something" at the researcher's choice and their results are monitored.

Using randomization:

The origins of contemporary statistics can be traced back to Sir Ronald Aylmer Fisher, who made contributions to comprehending randomization.

Controlled by a placebo:

Placebo controlled is another crucial term to comprehend. A placebo is a "inert" alternative. for an intervention or therapy. "Inert" refers to a compound's lack of recognized action that could influence the result.

Another name for blinding is masking:

This is yet another crucial term to comprehend.When it is possible for the result to be influenced by Blindness is crucial when it comes to the expectations of the patient or researcher. There are three different forms of blinding: single blind, which occurs when the patient is blind, double blind, which occurs when both the patient and the researcher are blind, and triple blind.

Blind: when the investigator, patient, and data cleanup personnel are all blind.

2. LITERATURE REVIEW

A Systemic review of (51) journals - Including: (Journal name, Title of the article, Page no., ISSN no., Pharmacological action), published articles from various online portals.

3. OBJECTIVES / AIMS

- To Identify the effects of Azadirachta Indica on the Prover with the help of a day book.
- To analyse the symptoms observed after the compilation from the day book.

4. RESEARCH METHOD / METHODOLOGY

4.1 Research Design: This study employs an exploratory research design to evaluate the success of microfinance and PMMY.

4.2 Data Collection Method: Secondary data on PMMY will be collected from official reports, different publications of the Ministry of Finance, reports of the Reserve Bank of India, and the dataset from MUDRA. This will yield quantitative information on the overall loan disbursement, default rate, and demographic data of the borrowers.

4.3 Sampling Method: Convenience Random Sampling Method.

4.4 Study Design:

Double Blind Randomized, Placebo-controlled study, Parallel design.

4.5 Study Setting:

The study will be undertaken at Bharati Vidyapeeth (Deemed to be University) Homoeopathic Medical College, Pune.

4.6 Investigational Medicinal Products:

Azadirachta Indica is a medicine that has been used as a choice of drug for drug proving on Healthy provers.

4.7 Selection of Materials:

The Homoeopathic drug Azadirachta Indica will be purchased from G.M.P. approved Homoeopathic pharmacy (DR. Willmar Schwabe Pvt Ltd. Noida). A randomized, double- blind, placebo-controlled study was conducted at Bharati Vidyapeeth (Deemed to be University) Homoeopathic Medical College, Pune.

4.1 Route of administration:

Oral Route

4.8 Sample size:

40 Provers. Group 1 (placebo) and group 2(Azadirachta indica). (25 Provers - Drugs, 09 Provers - Placebo, 06 provers - Dropout)

4.9 Sampling technique:

Simple Randomization Double Blind Placebo Control Trial.

4.10 Inclusion criteria:

1. Age: 18 - 60 years
2. Both guys and females
3. Healthy people with no obvious illness and typical unbiased.

4. Laboratory boundaries during screening Savvy to the point of recording cautiously current realities, abstract and objective Side effects created by the medication during demonstrating. Ready to be educated regarding the idea of the review and able to give Composed informed assent.

4.11 Exclusion criteria:

1. Any illness or condition which could think twice about hematopoietic, renal, endocrine, Aspiratory, focal sensory system, cardiovascular, immunological, dermatological, Gastrointestinal or some other body framework.
2. Persons with visual impairment. People who have gone through a medical procedure over the most recent two months. Arranged clinical/dental treatment during the demonstrating time frame including home grown or dietary enhancements, methods, or prescriptions that are probably going to disrupt, or considerably change, responsiveness to the demonstrating substance.
3. Volunteers on standard prescription (Allopathic, Ayurvedic, Homeopathic, Naturopathic, Unani, and so on) for any intense or persistent sickness.
4. Participants should not be on any homeopathic cure in the previous month and have had no massive change in wellbeing status somewhat recently.
5. Emotionally upset, crazy, or restless people. People having a known history of sensitivities, food touchiness, and so forth.
6. Women during pregnancy, puerperium, and keeping in mind that breastfeeding, and ladies who have gone through hysterectomy. No Terrible Hobbits.
7. Recent history of liquor abuse/chronic drug habits or improbable to forgo extreme liquor utilization/drug admission during the review time frame Cooperation in another clinical or demonstrating preliminary during the most recent a half year.

4.12 Data collection procedure:

-Screening of volunteers (form a)

-Written voluntary informed consent (form b part 1-2)

-Pre-medical examination trial P.M.E (Pre-Medical Examination)

-Post-medical examination trial P.M.E (Post-Medical Examination)

-Photographic record

-The Globules were medicated with medicine.

-Each prover was given a start date and a convenient daily contact time.

-For two weeks, the provers daily noted the typical condition in their daybook. This acted as an observation phase before to prove in order to create a baseline and personal control for each prover.

-When no new symptoms or indicators appeared after three weeks, the proving was said to have been over. After then, each person's daybooks were collected.

-The data thus obtained was analysed using the George Vithoulkas grading system.

5. DATA ANALYSIS:

Cumulative score of the Vithoulkas grading scale symptoms Grade Symptoms Table no.01

Symptoms	Grade
Difficulty in urine	6
Bodyache	5
Itching all over head	3
Dandruff on frontal resion	3
Sleep satisfactory	2
Numbness	2
Feverish whole day	2

Table no.02

Particulars	Symptoms

Mind	Prefer sound music, discomfortable, Sluggishness, Drowsiness, want to be magnetised
Head	Itching all over the body, Dandruff, Itching of forehead
Eyes	Acrid , lacrimation
Nose	Sneezing
Mouth	Tongue ulcer
Stomach	stomach ache, Thirst for hot water, Desire for potato
Rectum	Mucus mixed stool, Increase urge for cough during diarrhoea
Urinary	Painful micturition
Cough	Cough with sticky sputum
Extremities	Leg-sided leg pain, Knee joint pain, Difficult to walk
Sleep	Sleep unsatisfactory
Fever	Tiredness, Feverish feeling
Skin	Itching all over the body

Potency 30C, Number of provers: 40

Researcher meetings – Daily bases.

After evaluation and study the drug picture of Azadirachta Indica was found.

6. CONCLUSION

Azadirachta Indica was identified for exploring its effects on human volunteers in a homoeopathic, potentized dose. The Potentization was carried out with documented force parameters. Further research on similar lines may help in Homoeopathic drug discovery. Further clinical trials and evaluations can enhance the strength of the current experiment and its outcome.

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Full Home Address with Pin code / Zip code : (First Author) :-

Name :- Dr.Anand pal singh kushwah House Number :- 104,,
Apartment/Street/Building :- Trinetra appartment
Area/Nearby place :- City /Village/ Town :- 150feet ring road Rajkot. District :- Rajkot
State :- Gujarat Country :- India
Zip Code / Pin Code: 360006
Mobile Number with country code: +7974840780