

## Study Protocol

### **Evaluation of Comparative Efficacy of *Jyotishmati* (*Celastrus paniculatus* Wild) and *Yastimadhu* (*Glycyrrhiza glabra* Linn) in Enhancing IQ and Memory of Different *Prakriti* School Going Children-A study Protocol of Double Blind Randomized Clinical Trial**

#### **Abstract:**

**Background**-Education plays a major role in life, whereas lack of intelligence, learning, and memory will lead to failure in school performance and school dropout. Medhya drugs are used frequently to enhance the memory and IQ in children. Jyotishmati and Yashtimadhu are medhya (IQ-enhancing & memory-booster) drugs, described in numerous classical texts of *Ayurveda*. However, comparative efficacy and randomized trials on various prakriti types have not been studied. Thus, to assess the comparative efficacy of *Jyotishmati* in enhancing IQ and memory in relation to *Yastimadhu* as standard control, this research has been planned. **Objective:** To evaluate the efficacy of Jyotishmati on IQ and memory, and compare the efficacy with that of Yastimadhu in children with different prakriti types. **Methodology:** It will be conducted on healthy school-age children of 8-13 years, recruited from CBSE schools near Mahatma Gandhi Ayurved College, Hospital and Research Centre, Salod, Wardha. The study will be a randomized, standard-controlled, double-blind, parallel group clinical study. All participants will be randomly divided into two groups, each of 30 individuals; each group is subdivided into three subgroups of 10 individuals each. One group will be given *Jyotishmati* while the other will be given *Yastimadhu*, both in granule form. IQ assessment will be done by using the Draw a Man test and the PGI memory scale for memory assessment. **Expected Results:** This study will validate the efficacy of *Jyotishmati* and *Yastimadhu* in enhancing IQ and memory, and it will give detailed information about their efficacy in different *Prakriti* dominant children. **Conclusion:** This study will provide unique information to increase awareness of the administration of Medhya drugs according to Prakriti, as well as knowledge about which drug is best for improving either IQ or memory, or both.

**Keywords**-Medhya drugs, IQ, Memory, Prakriti, Jyotishmati, Yastimadhu, children.

## **INTRODUCTION**

The important building stage of a person's career, earning, and life as a whole is education. Poor school performance, early school dropouts, and, eventually, poor economic conditions will result from poor intelligence, learning, and memory issues[1]. There are various interventions and methods available for early diagnosis and treatment to increase the academic performance of such children[2]. Various herbal nootropic agents' use is one of the recent advancements in this field. These nootropic drugs have been proven to be effective in enhancing learning, memory, and cognitive capabilities, and thus are being employed in poor learning and in problems related to memory and low IQ. These nootropic drugs are *Jyotishmati*(*Celastrus paniculatus* Wild) and *Yastimadhu* (*Glycyrrhiza glabra*, Linn) taken for this study. *Yastimadhu* was described as *Medhya* by Acharya Charaka[3], Sushrut[4], and Vagbhat[5], but Kaidev Nighantu[6], Dhanvantari Nighantu[7], Raj Nighantu[8], and Bhavaprakash Nighantu[9] specifically mentioned *Jyotishmati* as *Medhyadravyas*. Recently, in animal studies, it has been proven that the enhancing cognition action as well as the memory function of *Jyotishmati*[10] and *Yastimadhu*[11]. There are no conclusive randomised clinical trials to validate their *medhya* efficacy as per *prakriti* in children. These herbal nootropic *medhya* drugs are widely used without proper consideration of Ayurveda principles, which could lead to misuse. One of the important *Ayurvedic* principles is the assessment of *Prakriti*, and drugs should be used according to *Prakriti* types. Due to the high demand for nootropic drugs, they are randomly used without proper analysis of the *prakriti* of a person and, hence, may not achieve the optimum efficacy desired. Ideally, we need to prescribe herbs as per *Prakriti* and other principles to augment the efficacy. This study will address the rational use of *Prakriti*-based nootropic drugs by enhancing their action and outcome. Using *Jyotishmati* and *Yastimadhu* as examples, we did not find any research work done on a *prakriti* basis to evaluate the association between memory and IQ. Thus, to assess the comparative efficacy of *Jyotishmati* in enhancing IQ and memory in relation to *Yastimadhu* as a standard control, this research has been planned.

## NEED FOR STUDY

Intelligence and memory have a close relationship and both play an important role in various developmental areas during childhood, but till date these have not been compared in a single study. Those who have good intelligence and memory are more successful in school, work and social life[12]. Thus, IQ and memory are important factors in day-to-day life. Various research has been done on different *Medhya* drugs for enhancing IQ and memory separately. But no research has been found on correlative study of *Jyotishmati* and *Yastimadhu* based on *Prakriti* in

children. Thus, this study has been planned to understand the IQ and memory correlation of a child, based on their *Prakriti* dominant.

### RESEARCH GAP ANALYSIS:

*Jyotishmati* and *Yastimadhu* are both described as *Medhyadravyas* in classical text. However, no study till date has been done to compare IQ and memory **together** in children with **different Prakritis**. As in Ayurveda it has told that *Bhaisaja*(drug) should be given by proper assess of prakriti, desha, kala etc. Thus, this study will establish the effect of medhya drugs (*Jyotishmati*&*Yastimadhu*) and estimate the effect equivalence of these two drugs.

### AIM AND OBJECTIVES:

#### AIM:

To evaluate the comparative efficacy of *Jyotishmati* and *Yastimadhu* Granules in enhancing IQ and memory in school going children having different *Prakriti* - A double blind randomized clinical trial.

#### OBJECTIVES:

##### Primary:

1. To evaluate the efficacy of *Jyotishmati* on IQ and memory in children with different *Prakriti* types.
2. To evaluate the efficacy of *Yastimadhu* on IQ and memory in children with different *Prakriti* types.

##### Secondary:

1. To find out relative prevalence of various types of *Prakriti* in study population.
2. To find out patterns and association of IQ and memory in different *Prakriti* types.

### RESEARCH QUESTION:

Whether *Jyotishmati* is as efficacious as *Yastimadhu* in enhancing IQ and memory in children of different *Prakriti*?

### REVIEW OF LITERATURE:

Sr. no	Text	Sthana	Adhyaya		Topic	Shloka page no.
			No			
			.			

1.	<i>Charakasamhita</i>	<i>Chikitsasthana</i>	1,3	<i>Rasayanaadhyaya,</i>	<i>Rasayana, Medhyarasayana</i>	7-8,30-31
2.	<i>Charakasamhita</i>	<i>Vimanasthana</i>	7,8	<i>Rogabhisajit iyamvimana m,</i>	<i>Prakruti, v ataprakru ti</i>	123,98
3.	<i>Sushrutasamhita</i>	<i>Shareerasthana</i>	4	<i>Garbhavyaka ranasharira</i>	<i>Saptaprakruta, vat ajaprakru ti, pittaprakru ti</i>	62,63,67,68
4.	<i>Vagbhataastangahridya</i>	<i>Shareernasthana</i>	3	<i>Angavibhaga sariram</i>	<i>Kaphaprakruti</i>	96-103
5.	<i>Kaidevnighantu</i>		1	<i>Aushadhivar ga</i>	<i>Jyotishmati- Medhya</i>	11
6.	<i>Dhanvantarinighantu</i>		1	<i>Guduchyadiv arga</i>	<i>Jyotishmati Guna, Ya stimadhu guna</i>	5-6,138-139

## MATERIALS AND METHODS:

### Source of data/ Place of study:

Healthy volunteer children recruited from CBSE schools near Mahatma Gandhi Ayurved College, Hospital and Research centre, Salod, Wardha.

**Study types:** Interventional study.

### STUDY DESIGN:

**Study design:** Randomized, standard controlled, double blind, parallel group clinical trial.

The study will be randomized, standard controlled double blind, parallel group clinical study on healthy volunteer children between 8-13 years.

### Drug collection/authentication

Raw materials required for the preparation of *Jyotishmati* granules and *Yastimadhu* granules will be procured from *Dattatrayarasashala* and organic jaggery and cow ghee will be taken from

(AGMARK certified company).It will be authenticated by Department of *Dravyaguna*, MGACH&RC, salod(H)

### Method of preparation:

The common method of granules preparation is as follows;

2 parts of jaggery is heated in a vessel till it melted.



Add 1 part of (*Jyotishmati, Yastimadhu*) fine powder and heat until it become mass



Add 1/10 of cow ghee to the mass



The mass is kept in granulating machine to get the granules



The granules are kept in drying machine to dry



Thus,formed granules will be sealed and packed in container.

### SAMPLING TECHNIQUES:

Equal number of participants (Gender, Age, *Prakriti*) will be kept in each group.

Randomize through table of random number or computer-generated random allocations software method to avoid bias.

**SAMPLE SIZE:** The sample size is calculated according to the effect size from the previous study [13]. For this study we are using by the following formula:

Formula:

$$n_1 = \kappa n_2,$$

$$n_2 = \frac{(z_{\alpha/2} + z_{\beta})^2 s^2 (1 + 1/\kappa)}{(\mu_E - \mu_C - \delta)^2}.$$

- Fixed Scenario Elements

### DISTRIBUTION INTO GROUPS:

The children with dominant *dwidoshajPrakriti* will be divided into two groups(A and B). Each group has three sub-divided group with three dominant *Prakriti.eVatapitta, Pittakapha, Kaphavata*.Out of which, Group B will be given *Jyotishmatigranules*andGroupA will be administered *Yastimadhu* granules as standard control. Each group will be having 30 participants, 10 in each subdivided group.Thus, whole study is planned upon a total 60 healthy school age children.

### Intervention

Group B will be given *Jyotishmati* granules while Group Y is given *Yastimadhu* granules both with milk in dose as per age in two divided dose. Granules will be made of study drug i.e *Yastimadhu* and *Jyotishmati*, with use of jaggery and cow ghee. The drug will be given continuously for 60 days.

	<i>Jyotishmati</i> granules (Group B)	<i>Yastimadhu</i> granules (Group A)
Types of formulation	Granules	Granules
Dose	As per Young's formula / 1BD	As per Young's formula / 1BD
Route of administration	Oral	Oral
Time of administration	Twice daily 5AM & 7PM	Twice daily 5AM & 7PM
<i>Anupana</i>	Milk	Milk
Duration	60days	60 days

**Posology: Dosage fixation** as per Young's Formula for (*Jyotishmati granules and Yastimadhu granules*) Child dose = Adult dose x age in years of child

Age in year +12

If Adult dose of *Choorna* is 5 gm (As per Classics) then dose of *Jyotishmati* granules and *Yastimadhu* granules for children will be as follows. As we are using it in granules form, we will take double dose of *Choorna*.

For **8-years child** it is, Child dose =  $5 \times 8 / 20 = 2 \text{ gm} \times 2 = 4 \text{ gm} \approx \mathbf{4 \text{ gm}}$

For **9-years child** it is, Child dose =  $5 \times 9 / 21 = 2.142 \text{ gm} \times 2 = 4.284 \text{ gm} \approx \mathbf{4.3 \text{ gm}}$

For **10-years child** it is, Child dose =  $5 \times 10 / 22 = 2.272 \text{ gm} \times 2 = 4.544 \text{ gm} \approx \mathbf{4.6 \text{ gm}}$

For **11-years child** it is, Child dose =  $5 \times 11 / 23 = 2.39 \text{ gm} \times 2 = 4.782 \text{ gm} \approx \mathbf{4.8 \text{ gm}}$

For **12-years child** it is, child dose =  $5 \times 12 / 24 = 2.5 \text{ gm} \times 2 = 5 \text{ gm} \approx \mathbf{5 \text{ gm}}$

For **13-years child** it is, Child dose =  $5 \times 13 / 25 = 2.6 \text{ gm} \times 2 = 5.2 \text{ gm} \approx \mathbf{5.2 \text{ gm}}$

Which can be given in divided dose as per the *Agni, Dosha, Kala* etc. of the patient.

**Anupana:**Milk

**AushadhSevankala:**Twice daily 5AM & 7PM.

**Investigation:**NA

**Study duration:**60days.

**Follow up:**Follow up will be done after 120 days from the date of enrollment.

**INCLUSION CRITERIA:**

- Children of 8 – 13 years.
- Parents children who are willing to sign the consent form.

**EXCLUSION CRITERIA:**

- Children having either dominant single dosha *Vataj, Pittaj and Kaphaj Prakriti or sannipataj/Tridoshaj*one.
- Children having diagnosed mental illness, psychological disturbance, poor scholastic performance (inquiring with teacher for result).
- Children suffering acute or chronic illness and/or taking medications.

**WITHDRAWAL CRITERIA:**

- If children or parents later did not want to complete the study.
- Any illness that required hospitalization.
- Any severe adverse drug events.

**ADHERENCE MONITORING:**

The participants will be adhering to the study drugs and will be assessed by monthly follow-up and telephonic communications as well as assessment of drugs use at follow up through return of empty containers.

**PROPERTIES OF TRIAL DRUGS**

*Jyotishmati* (*Celastruspaniculatus*Wild) and *Yastimadhu* (*Glycyrrhizaglabra*Linn) are both described as *MedhyaRasayana* in ancient classics of *Ayurveda*. They are being used since ages for their nootropic action. The following table indicates their properties

Name of drug	Botanical name	Part used	Rasa	Guna	Veerya	Vipak a	Karma	Dosh prabhava
Yastimadhu[14]	<i>Glycyrrhiza glabra</i> Linn	Roots	Madhura	Guru Snigdha	Sita	Madhura	Tridosahara, Rasayana, Ursyacaksuya	Tridosahara
Jyotishmati[15]	<i>Celastruspaniculatus</i> Wild	Seed and leaf	Tikta, katu	Teekshna&snigdha	Usna	Katu	VataKaphahar, Medhyarasayana	VataKaphasamak

#### ASSESSMENT:

##### Prakriti Assessment [16]

- *Prakriti* of all the participants will be assessed before registering for the study.
- *Prakriti* will assess through “*PrakritiVichaya*” module of AyuSoft software of Centre for Development of Advanced Computing (C-DAC).
- The module possesses various questionnaire specific to age group and gender.
- It covers history, physiological & psychological, anatomical, assessment with practical options to each question.

##### Memory Assessment:

Memory will be assessed by “PGI MEMORY SCALE FOR CHILDREN”[17]. It consists of ten subtests, they are-remote memory, recent memory, mental balance, attention and concentration, delayed recall, immediate recall, verbal retention for similar pairs, verbal retention for dissimilar pairs, visual retention, recognition of common objects.

The main domain assessed will be:

- Working memory (immediate).
- Short term memory.
- Long term memory.

## **IQ ASSESSMENT:**

Draw-A-Man-Test [18]:

- The children will be given paper and pencil to draw a man according to their knowledge.
- The score is giving base on different body parts like eyes, nose, hand etc.

## **STATISTICAL ANALYSIS:-**

Assessment parameters will be subjected to Univariate and multivariate analysis using SPSS 21.0 VER with appropriate statistical methods.

- The data will be analyzed by using paired t-test & unpaired t-test for objective parameters and Mann-Whitney U test, Wilcoxon rank-sum test, one/two-way ANOVA tests for subjective parameters.
- Chi-square test for qualitative with the frequency of patients & unpaired t-test for quantitative.
- Test of hypothesis superiority analysis will be done through the application of appropriate inferential statistics

## **SAFETY RECORDING**

### **Adverse Drug Events:**

All adverse events with information of severity and any related to the study medication will be recorded. If there is serious adverse effect then immediately it will be notified to the study monitor.

### **Study schedule**

	<b>Baseline( 0 day)</b>	<b>120 Days</b>
<b>Informed Consent &amp; PIS</b>	<b>YES</b>	
<b>Medical History</b>	<b>YES</b>	
<b>Prakriti Assessment</b>	<b>YES</b>	
<b>Memory Assessment</b>	<b>YES</b>	<b>YES</b>
<b>IQ Assessment</b>	<b>YES</b>	<b>YES</b>
<b>Assessment of Drug Compliance</b>	<b>YES</b>	
<b>As per standard guidelines</b>		<b>As per standard guidelines</b>

### **ALLOCATION & BLINDING:**

The participants in both the group will be allocated randomly by computer generated random allocation software. In advance, the location sequences will be generated, and consecutively numbers sealed in opaque enveloped. By keeping both the interventions packing identical, the investigator and supervisor could not know about the interventions. Investigator (MD scholar) and supervisor will generate the allocation sequence and enroll participants as well and intervention will assign to them. This study is double blind, so after the assignment of intervention both the investigator & participants will be blinded.

### **OBSERVATION AND RESULT:**

Data obtained from the follow up chart and other observations and the results will be drawn on the basis of various charts, graphs, and tables.

### **SCOPE OF THE STUDY:**

It will be first comparative study on *Jyotishmati* and *Yastimadhu*. The result of the study will help practitioner in rationale use of both these drugs. According to the *Prakriti* of patient, it will further open the doors for new studies on various *Medhya* drugs to evaluate their differential effects on various types of *Prakriti*.

### **ETHICS AND DISSEMINATION:**

Ethical approval had taken from Institutional Ethical committee of MGACHRC, DMIMS (DU) and its reference number is-Ref. No. MGACHRC/IEC/July-2021/35 for this study. Trial of the study has been registered in clinical trial registry of India & number is CTRI/2021/09/036950.

After giving detail account of plan and objectives of the study, the written informed consent from the parents of the participants will be taken. Whatever findings in this study, articles will be published to display the result for the benefit of not only medical practitioners but also the whole society.

### **EXPECTED OUTCOMES/RESULTS:**

Through this study detail information about the efficacy of Jyotishmati and Yastimadhu in different prakriti children will be given. It will also demonstrate Ayurvedic concepts regarding IQ and memory of different types of prakriti.

## **DISCUSSION**

Medhya drugs are regularly used by Ayurveda pediatricians. Jyotishmati and Yastimadhu are among the medhya drugs. Both of these drugs are described in Ayurvedic classics. These drugs are used frequently by practitioners without knowing the exact indication in individual prakriti and in various diseases of IQ, memory, learning, behavior, etc. *Yastimadhu* (*Glycyrrhiza glabra*, Linn) has been clinically researched for its nootropic effects and has been verified to show results in IQ, memory, and learning. While clinical research on *Jyotishmati* (*Celastrus paniculatus*) is less, it is equal to Yastimadhu for nootropic effect and has not been proven till this date. Still, there is a need for various Ayurvedic drugs to evaluate the optimum effect of drugs based on their prakriti types. The principle of Ayurveda clearly mentions that various medicines should be used on an individual basis and not fixed for everyone as a common practise.

Jyotishmati has been shown to be highly significant in improving neuronal function (Bhagya. V, 2020)[19]. and has shown highly significant backward digit span in one study (Dhodapkar SP, 2018)[20]. In another study, it has shown improvements in cognitive deficits (Srinibash.s, 2018) [21]. While Yastimadhu has shown high significance in improving the functional aspects of buddhi and IQ (Sriharisheshagiri, 2015)[22] in another study it has been shown effective in improving neuropharmacological activity (A.K. Teltumbde, 2013)[23]. Formalised memory and intelligence show a significant relationship and also represent distinct functions. This has shown that various studies have been done on Jyotishmati and Yastimadhu separately and have shown significant results individually[24]. However, there is no study that has been done on Jyotishmati and Yastimadhu together on IQ and memory based on prakriti. As in Ayurveda, it is explained that *Bhaisaja* (drug) depends on prakriti, desha, kala etc. [25-27]. Thus, this study will establish the nootropic effect of Jyotishmati & Yastimadhu and also estimate the effect equivalence of both the drugs.

## **CONCLUSION:**

There are a lot of requirements to enhance awareness of Ayurvedic *Medhya* drugs in prakriti-based administration of drugs. The study will provide accurate information, particularly in this

part. For the sake of societal benefit, both of these medhya drugs will be utilised to their optimum effect.

#### COMPETING INTERESTS DISCLAIMER:

Authors have declared that no competing interests exist. The products used for this research are commonly and predominantly use products in our area of research and country. There is absolutely no conflict of interest between the authors and producers of the products because we do not intend to use these products as an avenue for any litigation but for the advancement of knowledge. Also, the research was not funded by the producing company rather it was funded by personal efforts of the authors.

#### NOTE:

The study highlights the efficacy of " Ayurved " which is an ancient tradition, used in some parts of India. This ancient concept should be carefully evaluated in the light of modern medical science and can be utilized partially if found suitable.

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