Executive Summary

Project title: Randomized controlled clinical trial to evaluate prophylactic properties of Ayurvedic Treatment Protocol in refractory and chronic migraine patients

Trial Registration Code: CT-57/011/RS

Project Code No.: N1343

Ethical clearance received on w.e.f.: 03-10-2011 (ref no. IEC/NP-276/2011)

Memorandum of Understanding (15-03-2012): Signed between Principal Investigator, Dean (Research) from AIIMS and Ipca laboratories ltd., Mumbai (Sponsorer)

Principle Investigator: Prof. Dr. Manjari Tripathi, Dept. of Neurology, AIIMS, New Delhi

Co-Investigators: Prof. Dr. A. K. Mahapatra, HOD, Dept. of Neurology, AIIMS, New Delhi and
Vaidya Balendu Prakash, Ayurvedic Physician

Held at: Department of Neurology, All India Institute of Medical Sciences, Delhi

Project duration: 1st April 2012 – 31st May 2016

154 patients suffering from refractory/ chronic migraine were enrolled in the study (Table 1). These patients were randomly treated in two stated groups; one with conventional prophylaxis (varied) and rescue and second with Ayurvedic prophylaxis, consisting of Narikel Lavan 1 gm BD, NUMAX 1 BD, Rason Vati 1 gm TDS and Godanti Mishran 250 mg OD for 4 months. No conventional prophylaxis was given to this group. Both the groups were allowed to take rescue treatment as and when required.

Table 1: Demography of enrolled patients (n = 154)

Particulars		Ayur Group (n = 77)	Conv Group (n = 77)
Sex (F : M)		53:24	58:19
Age Group		18-62	18-55
History (in years)		1-28	1-20
Frequency (monthly)	2-4	35	26
	> 4	42	51

Outcomes:

- Ayurveda shows promising results in the treatment of Migraine in comparison to Ayurvedic treatment
- The recovery time was shorter for the Ayurvedic group (Table 2)
- Significant reduction was observed in the frequency and intensity (Visual Analogue Score) of pain
- Migraine Induced Disability Assessment Score (MIDAS) was reduced significantly in the Ayurvedic group
- Sustainable and significant improvement was observed in the Ayurvedic group (Table 3 & 4)

Table 2: Treatment duration in both groups

Duration of treatment	Ayur Group (N = 70)	Conv Group (N = 76)	p-value
Day 120	70	35	
Day 150	0	20	
Day 180	0	21	
Median Duration	120	180	<0.001

Data represented as n (%); Chi square test and Wilcoxon rank sum test used for comparison and median duration comparison respectively

Table 3: Observation after 120 days (n = 146/154)

Particulars	Ayu Gr (70/77)	Conv Gr (76/77)	p-value
Moderate to Severe pain with need of medicines	35 (Rescue)	65 (Prophylaxis +Rescue)	<0.001
Mild pain with no need of medication	33	11	
Symptom free	2	0	
VAS (D 0/120)	631/347	632/375	<0.05
MIDAS (D 0/90)	3405/1883	2987/2165	<0.05

Table 4: Observation after 360 days (n = 146/154)

Particulars	Ayu Gr (70/77)	Conv Gr (76/77)	p-value
Moderate to Severe pain with need of medicines	0	14 (Rescue)	<0.001
Mild pain with no need of medication	56	62	
Symptom free	14	0	
VAS (D 0/360)	631/156	632/211	<0.05
MIDAS (D 0/360)	3405/557	2987/803	<0.05

Conclusion: Ayurvedic treatment was based on the treatment of *Sleshma pitta* (gastrointestinal reflux), contrary to the prevailing conventional approach which is majorly restricted to neurology. A pharmacological study conducted under **Prof. Dr. Y.K. Gupta, Department of Pharmacology, AIIMS, New Delhi (February 2011 – May 2016)** showed that the Ayurvedic formulations used in the treatment of Migraine showed no Analgesic effect, Anti-inflammatory effect, General CNS activity effect, Anti-Histamine effect, Anti 5 HT effect, general behavioural parameters, effects on hemodynamic effects and isolated tissue experiments, alone or in combination. Also, the efficacy of this innovative approach has now been proven by the results of this study. Further experimental studies are required to scientifically validate this hypothesis.

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August, 2017