

What's up at Vedic Lifesciences?



Sleep Study:
Corn-y, but Effective



Viral Venture



MCT Oil Comes
to the Rescue



Rat-ting Achievement
Against BPH



Ironing Out the
Deficiency



VEDIC'S SLEEP STUDY: CORN-Y, BUT EFFECTIVE

Vedic is recruiting for a study to identify the effects of a corn maize extract on sleep quality and mood state across 120 randomized participants ranging 19-73 years of age.

This extract stands out due to its distinctive qualities as a hormone-free natural supplement. It is recognized for incorporating biologically active compounds that have proven to bind to melatonin receptors with a 4-fold higher affinity for MT2 Receptor (Melatonin activates two high-affinity G protein-coupled receptors, termed MT1 and MT2, to exert beneficial actions in sleep, circadian abnormality, and more).



This double-blind, placebo controlled study aims to enhance sleep quality and promote feelings of calmness and mental peace in healthy, undiagnosed participants who experience regular episodes related to sleep in a period of 4 weeks. The primary issue is that, the Garmin watches which are utilized to measure sleep duration, do not register changes in duration when individuals are awake or experiencing disrupted sleep while remaining in bed. Another challenge encountered during the 8-14 days' run-in period was the withdrawal of participants who failed to provide sleep data for more than three random days. To overcome these challenges, we screened more participants than we intended to. Having said that, Vedic holds quite the expertise in sleep studies.

Another study that we are currently running uses polysomnography.



As per our clinical research trend analysis, we found that in a period of 5 years, a total of 103 sleep supplement studies were registered on the trial registry clinicaltrials.gov.

Majority of those studies were found to use lavender as an intervention followed by magnesium. Few other interventions were honey, kefir, beetroot juice, and CBD.

Team Vedic is looking forward to the results of this exciting new study.



VEDIC'S VIRAL VENTURE

In the past 5 years, as per [Clinicaltrials.gov](https://clinicaltrials.gov), 301 supplement studies have been done on Upper Respiratory Tract Infections, indicating this as popular area of research. Vedic has not only conducted Covid-related studies but also common cold, flu, immunity, and vaccine studies.

In an earlier common cold study, done at Vedic, the supplement failed to show any benefits over placebo because the study was not adequately powered and long enough. Learning from this experience, this new study is being conducted on 300+ participants over a period of 180 days. As and when a participant gets an episode, they report to the centre following which they undergo a Rapid Antigen Test (RAT) and Real-time reverse transcriptase-polymerase chain reaction (RT-PCR) test to rule out Covid19. Our research focuses on a polyphenol-based investigational product (IP) that assesses IgA levels through nasal swabs.

Our operational strategy involves recruiting participants first in coastal regions and subsequently moving north, selecting sites based on climate and recurrence patterns. Another very challenging aspect of the study is participant retention. This protocol requirement is challenging but our team has devised measures to improve participant retention.

WINNER
NUTRA
INGREDIENTS
AWARDS 2023

Vedic Lifesciences' study, **'Studies on a food supplement as immune enhancer to boost the efficacy of Covid19 vaccine'**, recently won the award for Best Nutrition Research Project category at the NutraIngredient Awards 2023. In this study, it is hypothesized that administration of 5-ALA-Phosphate + SFC in subjects vaccinated against Covid-19 could contribute in enhancing the targeted function of the immune system, which might lead to reactivation and/or increase of the vaccination response.



GUT FEELING? MCT OIL COMES TO THE RESCUE



Forty studies have been posted on CT.GOV over the last 5 years investigating the popular Medium Chain Triglyceride (MCT) oil, spread across different health areas like infant health, eye health, Parkinson's disease, etc. Vedic is doing a 60-participant, 8-week study to assess the efficacy of MCT oil on gut permeability by assessing the levels of Lipopolysaccharide Binding Protein.

One of the biggest challenges faced by Vedic in this study was its strict inclusion criteria. Out of 5 criteria i.e., waist circumference, triglycerides level, blood pressure, blood glucose, and HDL cholesterol, the participants were expected to meet at least three to be included in the study. This caused an increased screening failures beyond the anticipated 20%. But we don't give up easily. Currently, the sites are enrolling faster and the study is close to meeting its target. Vedic ends up doing at least 3-4 gut health studies every year, which makes us quite the experts.



VEDIC'S RAT-TLING ACHIEVEMENT AGAINST BPH

Benign prostatic hyperplasia (BPH) is one of the most prevalent benign tumors in men over the age of 40 years. Some of the crucial reasons for developing BPH are uncontrolled cell proliferation, oxidative stress, disturbed cell apoptosis, and inflammation.

Vedic Lifesciences designed a one-of-a-kind 28-day study to investigate the potential of a marine derived ingredient to mitigate BPH induced by Testosterone in 48 Sprague-Dawley rats. This is a first for Vedic as no major pre-clinical research had been done with marine sources for BPH conditions. The only major challenge faced by Vedic was getting the Histopathology done on the target organ (Prostate).



IRONING OUT THE DEFICIENCY

Our unique claim distinguishes our upcoming study, as it will focus specifically on 60 non-anemic individuals grappling with iron deficiencies. The paramount goal is to enhance iron levels through the introduction of a new supplement.

There are a staggering 145 iron supplement studies registered in the past five years on Ct.gov. These investigations span diverse subjects, ranging from non-iron deficiency cases, obesity, endurance, postpartum anemia, menstruation, menopause, to chronic kidney insufficiency.



This study will be conducted across multiple sites in India, with a primary focus on examining serum ferritin levels. We are not anticipating any major challenges during the 8-week study duration. The product's formula is designed with a gentle, nourishing blend of foods and botanicals, ensuring ease of digestion and a non-constipating effect. Other similar studies also measure Total Iron-Binding Capacity (TIBC), Transferrin Saturation (tSAT), Complete Blood Count (CBC), High Sensitivity C-Reactive Protein (hs-CRP), and monitor bowel movements.