



Vedic Lifesciences  
Clinical Research



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# TRIAL TRANSCRIPTS

A Peak at our Ongoing Studies

## Here's why Screen Time During the Pandemic Doesn't Look so Eye-conic for Kids

Lack of physical activity and longer study hours led to more digital exposure for the kids. Prolonged use of electronics and exposure to digital screens has been scientifically proven to cause eye strain, dry eye symptoms and in worst cases, even myopia! We are about to start recruiting for a clinical trial involving young kids who will assess the effect of the nutritional supplement on their eye fatigue against a placebo. The results of this study will be path-breaking as this area is not well substantiated in the Nutra industry. The team is excited for the study to begin!



## Winning is a Habit Best Developed Gracefully

We were given the opportunity to conduct not 1, but 3 human clinical studies for a botanical ingredient which targeted mental alertness and focus. The ingredient, made of the traditional *Alpinia galangal*, went on to win the Nutraingredients Award for 'Ingredient of the Year' in Sports Nutrition, at Vitafoods Europe, and subsequently at Vitafoods Asia. Our experts designed claims that were positioned to succeed.

The ongoing fourth study is on 60 healthy adults to see the longer-term effects of this caffeine amplifier ingredient. The study results will be published once they are out and currently its protocol is under development

## On a Sweeter Note

Diabetic neuropathy can get on one's nerves, quite literally! India may soon become the "Diabetes Capital of the World".

Vedic has completed and written up a 50-volunteer study to explore the effect of a US dietary supplement on neuropathic pain. The supplement contains popular ingredients that support nervefiber regeneration and reduce pain and numbness in the legs & arms.



Despite the pandemic scare, we did not experience any major hurdles in the recruitment for this trial. We have a rich database of top-notch diabetologists willing to participate in such studies. The study has positive results and the manuscript is currently underway

## Exercise-induced Knee Pain? Is that a thing?

Knee pain and stiffness is a common problem for people suffering from osteoarthritis and similar conditions. However, the supplement industry is moving towards the sports nutrition segment in which 'clinical evidence on healthy individuals' is trending. Consumers of such joint health supplements are interested in learning more about how the product works on healthy adults who regularly exercise. Vedic is currently recruiting for one joint health study, for a popular US-based supplement - this works on relief from joint discomfort, at a clinically relevant daily dose. This 300 subject healthy volunteer study will be done in comparison with a placebo and another popular ingredient combination in the same health category. Even though healthy volunteers are easier to recruit compared to condition-specific participants, they're harder to retain in a long-duration study. However, the study team will try its best to adhere to the promised timelines. Our in-house team consists of experienced orthopedic doctors with large networks and a passion for clinical research. With this in mind, we can't wait to begin screening next month!





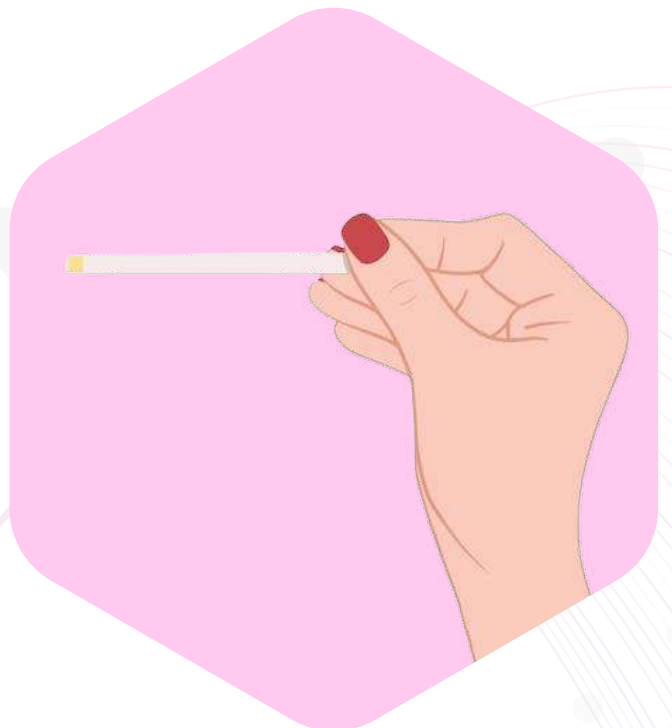
## Vaccine-associated Immunity: How Can This Be Enhanced?



A study by Innova Market Insights mentions that "60% of consumers seek foods & beverages that support their immune health". This clinical trial focuses on the effects of an innovative German-Japanese supplement on the anti-body levels of fully vaccinated individuals in India. More than 86% of the population of this vast and diverse country is fully vaccinated with the COVID-19 vaccine. This 160 subject study was completed in record time across 4 vaccination centers in India. We also recorded pharmacovigilance for this study.

## More Reasons to Love Probiotics

Probiotic products have diversified from their initial core usage for gastrointestinal health to a much broader range of benefits, including skin health, sports performance, and more female-focused areas like pregnancy, vaginal health, and urinary tract infections. This study measured the effectiveness of a probiotic in maintaining vaginal pH and checking dryness.



## More Than Just Skin Deep

Pollution, stressful lifestyles, and UV damage are known to accelerate skin aging. Moreover, it is a well-established fact that skin moisture is paramount to youthful-looking healthy skin. Considering these statistics, it doesn't come as a surprise that there was a whopping 61% increase in beauty-positioned supplement sales in the US last year. We decided to tap into this opportunity, focusing our next study to beauty and personal care. We have submitted the manuscript of the study details and data for an 8-week study for a Swiss nutricosmetic ingredient supplier -it involves the measurement of Trans Epidermal Water Loss (TEWL) using the Tewameter which is the world's most accepted measuring device for the assessment of Skin barrier functions. Skin barrier function helps in maintaining the skin hydration levels.



## Common Cold and Immunity

Ever since the outbreak of the COVID-19 pandemic, illnesses involving the upper respiratory tract have become increasingly common. The pandemic had got us all locked up in our respective homes, making it challenging to recruit volunteers with upper respiratory tract symptoms for such common cold studies. People wanted to avoid getting tests done at all costs, resulting in the overall reduction of doctor visits for mild symptoms like these.



20+ years of experience in this field, have put us in touch with large networks and patient pools of our sites which helped us recruit for such studies. The sites pre-screened the volunteers for mild symptoms and checked their previous contact with COVID positive individuals. Since health is our topmost priority, we also did temperature checks and followed all the sanitary protocols required in such cases. In case any of the volunteers developed serious symptoms, they were immediately withdrawn from the study, and appropriate actions were taken. These clinical trials have been very beneficial for the sponsors in today's times as they measure a variety of clinical outcomes – both objective like IL-6, CRP, TNF-alpha and subjective markers like the number of sick days.

## Pediatric Studies

Infantile colic is one of the major challenges of parenthood. It is one of the common reasons parents seek medical advice during their child's first 3 months of life. Colic is a poorly understood phenomenon affecting up to 30% of babies. Believe it or not, it's also considered to be one of the factors leading to postpartum stress and depression for mothers!



This particular study done for a US-based company was challenging as we had to ensure that the mothers are stay-at-home moms living in urban areas. They needed to constantly monitor their babies for crying time and fill in the questionnaires, whenever required. Moreover, it was a 21-day long treatment, requiring equal amount of patience from the babies. To ensure speedy recruitment and smooth study progress, our best project lead had been assigned to this study. We were also conducting this trial at well-known pediatric hospitals with highly trained personnel. The study is completed.

# Transcript

# SNAPSHOT OF CURRENT CLINICAL TRIALS AT VEDIC LIFESCIENCES

Study Health Area	Sample Size	Target Market	Condition	Tools
Gut Health	300	USA	IBS	ROME-IV, Abdominal Pain Severity Numeric Rating Scale: APS-NRS, Bristol Stool Scale, 16S rRNA sequencing
Sports Nutrition	30	Global	Resting Energy Expenditure (REE)	Indirect Calorimetry on the highly specialized Cortex Metamax
Bone & Joint Health	200	Australia & USA	Knee OA	100-point VAS, WOMAC for Pain, Stiffness and Physical function, SF-36 for QOL and the OMERACT-OARSI Responder Index
Weight Management	144	USA	Weight Loss	DEXA, waist hip ratio, total cholesterol, LDL,HDL, Serum-free testosterone, salivarycortisol, adiponectin: leptin ratio, appetite assessed by serum leptin and ghrelin levels,fasting blood glucose, HOMA-IR, Profile of Mood State questionnaire (POMS), BMI, Perceived Stress Scale, Gastrointestinal QOL Index
Cognitive Health	60	Global	Mental Alertness, Focus & Attention	Long term safety - Cardiogenic events assessed by ECG Long term efficacy – Alertness by Bond and Lader VAS, Sleep quality by Pittsburgh Sleep Quality Index (PSQI)
Metabolic Health	50	USA	Diabetic Neuropathy	Nerve Conduction Velocity Test, Doppler Ultrasound test and the 6-minute walk test
Heart health in Sports	40	Global	Aerobic fitness	VO2Max
Eye Health	60	Japan	Eye Fatigue	Convergence Insufficiency Symptom Survey (CISS), Visual Acuity Test
Vaccine Study	160	Germany	Immunity	Immunoglobulin G, VAS, EQ-5D-5L Scale





## What's Hot In Tox?

Our current toxicity studies include the general toxicity protocols for determination of oral LD50, 28 days repeated dose toxicity studies, 90 days repeated dose toxicity studies, developmental toxicity studies, and mutagenicity studies including the AMES and MNT tests, recommended by the OECD guidelines.

## Preclinical Efficacy Studies

### Effect of CBD on the Neurobehavioral Activity in a Stress-Induced Model in Sprague Dawley Rats



It may seem surprising, but Cannabidiol (CBD) has been highly recognized and consumed for various health benefits, over the years. Some of these include, reducing diabetic complications, alleviating anxiety and depression, reducing pain, Neurological diseases and the like. Vedic has successfully conducted a study to assess the effect of CBD on Neurobehavioral Activity, known as the Elevated plus-maze test model, Open Field Test, Despair Swim Test, Light-Dark Model) on Stress-Induced Sprague Dawley Rats



## 90 Day Repeated Oral Toxicity study of Fish Oil in Sprague Dawley Rats with 28 Day Recovery period

Fish oil, especially Omega-3 fatty acid, can be magical for your health. It contributes to typical brain and eye development and fights against inflammation, preventing heart disease. Vedic has designed a study to assess and evaluate the potential toxicity of Fish Oil containing Very Long Chain Fatty Acids (VLCFA) in Sprague Dawley Rats when administered for 90 days through an oral route with a recovery period of 28 days. The study is intended to generate information on any major toxic effects, target organs, the possibility of cumulative effects and an estimate of the No Observed Adverse Effect Level (NOAEL)/No Observed Effect Level (NOEL)/Low Observed Adverse Effect Level (LOAEL)/Maximum Tolerated Dose (MTD) as applicable.



## Anti-Diabetogenic and Anti-Obesity Activity of Test Item in High Fat Diet Fed C57bl/6 Mice

Diet-Induced obese mouse models have been used in a wide variety of studies that have aimed to reverse the symptoms of Type 2 diabetes. Since polygenic models of obesity do provide a more accurate model of the human condition, this study is designed to understand more about the interplay of obesity and glucose homeostasis or study diabetic complications. Among others, the study will analyze the obesity / diabetes biomarkers like Insulin, Leptin, Ghrelin and similar Adipokines, along with Oral Glucose Tolerance Tests and Insulin Tolerance test.

# SNAPSHOT OF PRECLINICAL ONGOING STUDIES

## Efficacy Studies

Types of Study	Guidelines	Product
Efficacy study of 80% CBD on Neurobehavioral Activity over Immobilization Stress-Induced Rat model	As per protocol	Broad spectrum NLT 80% CBD
Anti-Diabetogenic and Anti-Obesity Activity of Test Item in High Fat Diet Fed C57bl/6 Mice	Customized Study Design	Phenolic Compound

## Toxicity Studies

Types of Study	Guidelines	Product
14 Day Repeated Dose, Maximum Tolerance Study	As per protocol	Marine Ingredient
90 Day Repeated Dose, Maximum Tolerance Study	OECD 408	Marine Ingredient
14 Day Repeated Dose, Maximum Tolerance Study	As per protocol	Dietary Supplement
90 Day Repeated Dose, Maximum Tolerance Study	OECD 408	Dietary Supplement
Bacterial Reverse Mutation Test	OECD 471	Insect Protein
Acute Oral Toxicity	OECD 423	Insect Protein
In Vitro Micronucleus Test	OECD 487	Insect Protein
14 Day Repeated Dose, Maximum Tolerance Study	As per protocol	Insect Protein
90 Day Repeated Dose, Maximum Tolerance Study	OECD 408	Dietary Supplement / Nutraceutical Product
Bacterial Reverse Mutation Test	OECD 471	Dietary Supplement / Alternative Medicine
In Vivo micronucleus test	OECD 474	Dietary Supplement / Alternative Medicine
In Vitro Mammalian Cell Gene Mutation Assay	OECD 490	Dietary Supplement / Alternative Medicine

# COMPANIES THAT TRUST VEDIC LIFESCIENCES



## COMPANIES THAT TRUST VEDIC LIFESCIENCES



gaia  
HERBS



HEALTHY  
DIRECTIONS



HEMPRISE



HS  
Honest Science



HPI  
HP Ingredients  
Delivering Herbal Science Since 2001



INCRENOVO



INNOVAFEED



interpath



layn  
Natural Ingredients



Lonza



mibelle  
GROUP



Natreon  
Trusted Science, Naturally™



NNB



novozymes



NU SKIN



NuLiv Science



nuvamid



OmniActive  
HEALTH TECHNOLOGIES



PELAGIA™



photonamic



PureCircle  
by Ingredion



SBI Holdings



SOPHIM



SPECTRUMS  
EUROPE



Synergia  
Life Sciences



TSI



UAS Labs  
The Probiotic Company



VasoCorp  
Health Through Innovation