

Siddha Newsletter



Volume 8, Issue II
(July 2024 to June 2025)

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Faculty of Siddha Medicine,
University of Jaffna.

1. Activities by the Faculty

1.1 Upgraded to the Faculty of Siddha Medicine

The Unit of Siddha Medicine was officially upgraded to the Faculty of Siddha Medicine on 26th July 2024, marking a significant milestone in its academic and administrative development. The Faculty now comprises eight specialized departments, thereby strengthening its capacity for teaching, research, and clinical training. The newly established departments include:

- ✂ Department of *Moolathathuvam*
- ✂ Department of *Gunapadam*
- ✂ Department of *Manitha Uyiriyal*
- ✂ Department of *Noi Naadal Chikitchai*
- ✂ Department of *Sirorogam & Aruvai Maruthuvam*
- ✂ Department of *Nanjiyal & Paramparai Maruthuvam*
- ✂ Department of *Samooganala Maruthuvam*
- ✂ Department of *Kuzhanthai & Mahalir Maruthuvam*

This upgrade enhances the Faculty's ability to deliver comprehensive Siddha medical education and promote traditional healthcare knowledge through dedicated departmental focus. The Faculty of Siddha Medicine will serve as a significant resource for the undergraduate and Postgraduate students in enhancing their knowledge in Siddha Medicine and the unit will be oriented towards the preservation and the study of preventive and curative aspects of diseases, philosophy, religion, spiritual, yoga, culture and natural products of usages in health care systems and the proper understanding of the sacred text and manuscripts. Palm ola Manuscripts, ancient Siddha books and manuscripts are in Tamil stanzas and are the treasures of Siddha Medicine and primary source materials for Siddha Medicine.



1.2 Workshop on Varma

The Department of *Samooganala Maruthuvam*, together with the Well-being Centre of Vavuniya Campus, conducted a four-day Workshop (Resource person - Dr.V.K.Ramasamy, India) on Varma from 14th to 17th October 2024. Organized for the benefit of Siddha Medical Officers and Traditional Doctors, the programme offered practical demonstrations and hands-on training to enhance clinical application of Varma techniques. A total of 70 participants benefitted from this intensive training.



1.3 Workshop on Quotation Process

The Faculty of Siddha Medicine, in partnership with the Staff Development Centre (SDC), successfully organized a workshop on the Quotation Process on 28th of November, 2024, at the Faculty Auditorium. The session took place from 10:00 AM to 1:00 PM and brought together all academic and non-academic staff members of the faculty.

The workshop was conducted by Mr. K. Sureshkumar, Bursar of the University of Jaffna, who shared his extensive knowledge and experience in university procurement procedures. His presentation covered key aspects of the quotation process, including regulatory requirements, documentation standards, common challenges, and best practices to ensure transparency and efficiency in procurement activities.

Participants were engaged throughout the session, taking part in discussions and clarifying practical issues related to handling quotations within their respective departments. Overall, the event proved to be highly informative and timely, contributing to a better understanding

of procurement responsibilities across the departments. Attendees expressed appreciation for the clarity and relevance of the session, highlighting its value in improving the faculty processes.



1.4 Medical camp at kilinochchi

The Department of *Kuzhanthai and Mahalir Maruthuvam*, along with *Sirorogam & Aruvai Maruthuvam* organized a Medical Camp and Awareness Programme on 12th December 2024 at mayavanoor, killinochchi. Heads, Academic staff of the faculty and doctors from provincial Department Indigenous Medicine, Mayavanoor, vaddakachchi community participated in the Medical Camp.



1.5 Medical camps at Kilinochchi & Mullaitivu

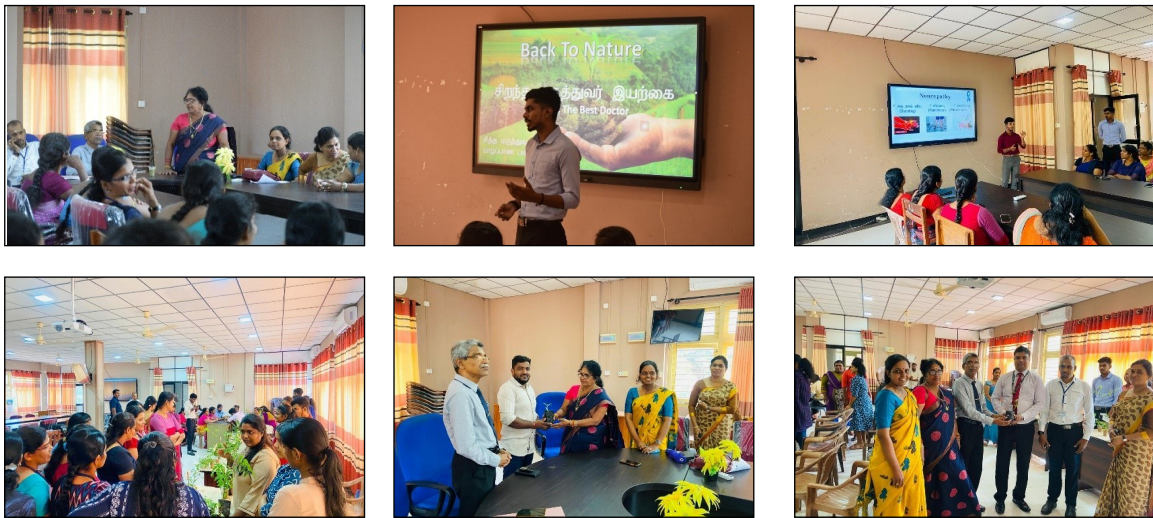
The Department of *Noi Naadal Chikitchai* coordinated medical camps in the Northern Province, held on 12th and 16th December 2024 in the Mullaitivu and Kilinochchi Districts respectively.



1.6 Community Outreach Programs on behalf of Faculty Inauguration

As part of the preparations for the Faculty Inauguration scheduled on 19th December 2024, the Department of *Gunapadam*, organized a series of meaningful community outreach activities on 12th and 13th December 2024.

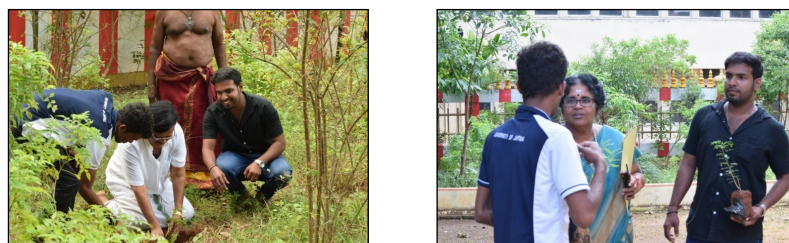
An awareness program was conducted at the Divisional Secretariat Office, Thenmarachi, focusing on the importance of medicinal herbs and introducing simple home remedies for maintaining health using locally available medicinal plants on 12th December 2024. The session received positive engagement from the community and local authorities. Around 25 medicinal plant nurseries were also distributed.



Continuing the initiative, on 13th December 2024, medicinal plant nurseries were distributed to the public across thirteen (13) Grama Niladhari Divisions in the Kaithady area, encouraging households to cultivate and utilize medicinal plants for daily wellbeing.



On the same day, *Natchathra Mooligaigal* (Star-associated medicinal plants) were planted at the Parameshwara Temple within the University of Jaffna, symbolizing the cultural and traditional value of these sacred plants. These programs collectively contributed to promoting herbal awareness, environmental sustainability, and the preservation of Siddha medicinal heritage ahead of the faculty's inauguration.



1.7 Joint Seminar on Food, Yoga, and Medicinal Plants

A joint seminar on Food, Yoga, and Medicinal Plants was conducted from 9.00 a.m. to 1.00 p.m. on 16th December 2024 at Faculty of Siddha Medicine. The program was collaboratively organized by the Departments of *Gunapadam*, *Samooganala Maruthuvam*, and the *Moolathathuvam*. The session of *Gunapadam* provided valuable insights into healthy living, traditional practices, and the significance of medicinal plants.



1.8 Faculty Opening Ceremony, Celebration of Agasthiyar Day & Inaugural Session of Orientation Programme

The Faculty Opening Ceremony, Celebration of Agasthiyar Day & Inaugural Session of Orientation Programme for the Academic year 2022/2023 were held on 19th December 2024 at the Faculty Auditorium. The programme commenced at 8.30 a.m. with the participation of Vice Chancellor, Deans of all the Faculties, Registrar, Bursar, Academic and Non academic staff of faculty, students, parents and distinguished invitees. The event was graced by Dr. Mohanadas, Chancellor, University of Vavuniya, as the Chief Guest. Faculty Opening Ceremony was coordinated by Dr. (Ms.)T.Thayalini &



Dr.(Ms.)V.Sanmugarajah; Celebration of Agasthiyar Day was coordinated by Dr.(Ms.) K.Sounthararajan and the Inaugural Session of Orientation Programme was coordinated by Dr.(Mrs.) S.Krishna & Dr.(Mrs.)V.M.Prasad. The programme featured traditional rituals, cultural performances by students, The ceremony also served to warmly welcome the new intake of students (2022/2023)

1.9 International Classification of Diseases(ICD-11) Workshop

The ICD-11 Traditional Medicine Chapter Module 2 Capacity Building Training Programme for the Faculty of Siddha Medicine, University of Jaffna, organized by the IR Unit in collaboration with the National Institute of Traditional Medicine (NITM), Department of Ayurveda, was held on 19th February 2025 at the Library Auditorium from 8.30 a.m. to 12.00 noon. The programme was coordinated by the Dr. (Ms.) V. Sanmugarajah, Senior Lecturer, Department of *Noi Naadal Chikitchai*, FSM. The programme was attended by Heads and Senior Lecturers of the Faculty, along with key officials including the Commissioner General of Ayurveda and representatives from the IR Unit and NITM. The session included welcome and opening remarks, presentations on the development, scope, and implementation of ICD-11 TM2, acknowledgements by programme coordinators, and an interactive discussion with final-year BSMS students, during which the ICD-11 Traditional Medicine Module 2 was formally introduced.



1.10 Medical Camp at Vavuniya

A medical camp was collaboratively conducted by the Department of *Noi Naadal Chikitchai* and Sirorogam and *Aruvai Maruthuvam* on 20th February 2025 at Vavuniya to provide basic healthcare services and promote health awareness among the community. A total of 57 beneficiaries (43 females and 14 males) received medical consultations, health screenings including blood pressure, blood sugar, BMI assessments, and free medications. Health education sessions on hygiene, nutrition, disease prevention, and healthy lifestyle practices were also conducted through interactive discussions and handouts. The camp successfully enhanced access to healthcare and improved community health awareness.





1.11 Women's Day 2025

The International Women's Day Celebration 2025 was successfully held from 8:30 AM to 12:30 PM on 08th March 2025 at the Siddha Faculty Auditorium. The event was organized by the Department of *Kuzhanthai and Mahalir Maruthuvam* in support with the Final BSMS students. The programme commenced with a series of traditional and spiritual rituals symbolizing wisdom, respect, and enlightenment, setting a meaningful tone for the celebration and highlighting the importance of women's well-being and empowerment.



1.12 Medical Camp at Nallur

A medical camp was organized by the Department of *Noi Naadal Chikitchai* collaboration with the Provincial Department of Indigenous Medicine at Nallur on 27th March 2025 with the objective of providing accessible healthcare services and promoting health awareness within the community. The camp benefited 73 individuals (21 females and 52 males). Services included basic health screenings such as blood pressure, blood sugar, BMI measurements, and medical consultations. Free medicines were dispensed as prescribed.

Health education sessions focusing on personal hygiene, nutrition, disease prevention, and healthy lifestyle practices were conducted through interactive discussions and handouts. The majority of

beneficiaries belonged to the 60–79 age group, highlighting the camp’s importance in addressing the healthcare needs of the elderly. Overall, the programme successfully enhanced community health awareness and access to Siddha medical care.



1.13 Awareness program for Children

the Department of *Kuzhanthai & Mahalir Maruthuvam* conducted a nutrition and health awareness programme on 1st of April 2025 at Parashakthi Day Care Centre, Kaithady. The programme focused on assessing the nutritional status and health conditions of children aged 4–5 years. Necessary guidance and advice were provided to the parents/guardians based on the assessment findings. A total of 40 children, along with their parents/guardians, actively participated in the programme.



1.14 Women’s Day 2025

Natural Wellness Society (PVT) LTD, Sri Lanka with the collaboration of Department of *Samooganal Maruthuvam* and JSA Section C (Medical Sciences) organized a one-day workshop titled “**Challenges and Work-Life Harmony of Middle-Aged Working Women**” on 29th April 2025 at Neithal Beach City, Navatkuli. The programme brought together participants from several districts of the Northern Province and focused on addressing work-life balance, health, and well-being of middle-aged working women. The event included a keynote address on time management, health education sessions, medical screenings for non-communicable diseases, holistic herbal treatments, and a yoga and meditation session. A nutritious millet-based food exhibition and lunch further emphasized healthy lifestyle practices. Overall, the workshop successfully raised awareness and provided practical guidance to support the physical and mental well-being of working women.





1.15 Monthly Seminar on Medicinal Herbal Plants – 2025

The Department of *Gunapadam* conducted monthly seminars on ‘Awareness of Medicinal Herbal Plants and Uses’ for schools in the Thenmaradchi zone. Sessions included a herbal garden tour featuring 500 medicinal plant species, a net house with 200 hill-station plants, and presentations by the second BSMS (39th batch) students on the health benefits of tropical fruits, cereals, and spinaches. Participants also received herbal porridge and medicinal plant nurseries.

The students and teachers from K/Muthukumaraswamy Maha Vidyalayam and J/Kaithady Nunavil Government Tamil Mixed College visited to the faculty of Siddha Medicine 11th April & 16th May 2025 respectively.



1.16 “Sahasak Nimavum” 2025-International Inventions & Innovations Competition & National Exhibition

The Faculty of Siddha Medicine, University of Jaffna, proudly participated in the “Sahasak Nimavum” 2025 – International Inventions & Innovations Competition & National Exhibition, organized by Sri Lanka Inventors Commission under the Ministry of Science and Technology on 25th - 27th April 2025 at BMICH, Colombo. The Faculty participated under the University Business Linkage (UBL) Cell and the event was coordinated by Dr. (Ms.) R. Sugeevan, UBL/ Faculty Coordinator. The team comprised UBL Faculty Coordinator, 2 Demonstrators and 17 enthusiastic students. This initiative was also supported and mentored by Dr. (Ms.) V. Sathiyaseelan, Dr. (Ms.) K. Sounthararajan and Dr. (Ms.) R. Sugeevan whose guidance played a key role in preparation of the invention products of the students.

Faculty's exhibition stall displayed a wide range of herbal products, (Hb Syrup, FENESCO Herbal

Soap, Basil Touch Cream, Incense Cone, Laser Beam Measurement Tool, Vegetable Cutter, Dhoop Rakshak, Sugar Veda, Nutri Butter Cookies, Clot Seal, Golden Glow Wash, Wiry Indigo Herbal Soap, Herbal Eyeliner and Blue Pea Anti-Dandruff Shampoo which attracted a number of visitors, including researchers, entrepreneurs, academicians, school students and the general public. The professionalism and creativity demonstrated at the stall highlighted the potential of traditional knowledge integrated with modern innovation.



1.17 Workshop on “Becoming Job Creator”

A workshop on “Becoming Job Creator” was organized by the UBL Cell, of the Faculty of Siddha Medicine, from 2.30 to 3.30pm on 16th May 2025, at the Siddha Medicine Auditorium. The 3rd, 4th, and Final BSMS students were participated in the workshop. The resource person Mr. Anu Ragavan, UBL Manager at the University of Jaffna, who shared valuable insights on patenting, start-ups, and spinoffs. The workshop was coordinated by Dr. (Mrs.) R. Sugeevan, UBL Coordinator, Faculty of Siddha Medicine.



1.18 Founder Member of the UBL-Jaffna Visited

Prof. Kanes Rajah, Founder Member of the UBL-Jaffna Advisory Board and Executive Director of the Center for Executives and Professional Development, UK, visited the Faculty of Siddha Medicine, University of Jaffna, on 22nd May 2025. The visit was organized by the UBL Manager, University of Jaffna, and coordinated by Dr. (Ms.) R. Sugeevan, UBL Coordinator of the Faculty. The program began with a meeting between Prof. Rajah and the Dean, followed by an interactive session with academic staff and the UBL team. Dr. (Ms) R.Sugeevan presented on the UBL Cell’s activities, ongoing

projects, start-ups, and future plans for innovation. The visit concluded with a student interaction session, during which Prof. Rajah shared valuable insights on entrepreneurship and innovative ideas related to traditional medical systems.



1.19 Gurupooja Day Celebration

The Department of *Moolathathuvam*, in collaboration with the Siddha Medicine Students' Union, successfully organized the sacred Siddhar Gurupooja celebrations at Sri Sidhivinayagar Temple / Siddha Medicine. The event, held on the following days, brought together Phase I BSMS students, Academic staffs of Department of *Moolathathuvam* to honour the great Siddhars who have contributed immensely to Siddha tradition and spiritual wisdom.

- Bhogar Siddhar Gurupooja Celebration on 26th of May 2025
- Kamalamuni Siddhar Gurupooja Celebration on 31st of May 2025
- Nandhi Devar Siddhar Gurupooja Celebration on 9th of June 2025



1.20 Seminar on Laboratory Biosafety and Biosecurity

The seminar on Laboratory Biosafety and Biosecurity to the laboratory staff and students those who are handling the laboratory practical was conducted by the Faculty Research Committee from 3 - 4.30pm on 6th June 2025 at Auditorium of Siddha Medicine. Dr.(Ms) N. Krishnapillai, Senior Lecturer, Department of Botany was invited as a resource person to deliver this seminar. The First, fourth



BSMS Students, Technical Officers, Temporary Demonstrators, Academic staffs were benefited from this seminar .

1.21 Environment Day

Environment Day 2025 was organized by the Department of *Gunapadam* from 8:30 AM to 12:00 PM on 13.06.2025 at the Faculty of Siddha Medicine, University of Jaffna. A total of 68 students and 5 teachers were participated from J/Kaithady Vigneshwara Vidyalayam and J/Navatkuli Tamil Maha Vidyalayam participated. Students visited the faculty herbal garden, observing 500 medicinal plant species and 200 hill-station plants in the net house. Dr. (Mrs.) V.M Prasad, Head/ department of *Gunapadam*, addressed the gathering, after which herbal porridge was distributed. The programme concluded with a presentation on environmental pollution, deforestation, and reforestation by the second BSMS (39th batch) students. Medicinal plant nurseries were distributed to the teachers and students to highlight the importance of plants in preserving the environment.



1.22 Awareness program for Women

The Department of *Kuzhanthai* and *Mahalir Maruthuvam* conducted a women’s health awareness programme with the support of Final BSMS Students on 18.06.2025 at Kodikamam Thirunaavukkasar Maha Vidyalayam. A total of 60 beneficiaries, including O/L and A/L female students and teachers were participated in this program. During the programme, essential health education and gynecological advice, along with appropriate solutions, were provided to the participants.



1.23 International Yoga Day -2025

1.23.1 At Siddha Teaching Hospital

To commemorate the International Yoga Day 2025, a special program was organized by the Siddha

Teaching Hospital Kaithady with the collaboration Ministry of AYUSH on 19th June. Faculty of Siddha Medicine. The event promoted physical, mental, and spiritual well being through the practice of yoga and to emphasize its significance in Siddha Medicine. The program witnessed enthusiastic participation from Department of *Moolathaththuvam* Temporary Academic staffs, 1st BSMS students, Siddha Medical officers & Intern Siddha Medical Officers.



1.23.2 At Faculty of Siddha Medicine

The Department of *Moolathaththuvam* and the Department of *Samooganala Maruthuvam* jointly organized the International Yoga Day 2025 celebration at the Faculty of Siddha Medicine on 21st of June 2025. The event highlighted the importance of yoga in promoting holistic health and well-being, reflecting the core principles of Siddha Medicine. Students, faculty members, and invited guests actively participated in this celebration. The program emphasized integrating traditional yogic practices into everyday life to enhance physical, mental, and social harmony.



1.23.3 At Thiruvalluvar Cultural Centre (JTCC)

Thiruvalluvar cultural centre (JTCC) came alive with the spirit of yoga as practitioners, University students to celebrate International Yoga Day 2025, organized by Consulate General of India. Department of *Moolathaththuvam* staffs and 20 Phase I BSMS students participated in this event. The students actively engaged in the practice of *Suryanamaskar*, various specific *asanas*, and Breathing exercises.



2. Outreach Activities

2.1 Seminar on “Yogavum Nalvalvum”

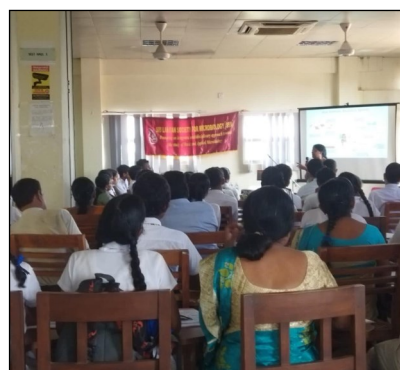
Dr.T.Thayalini organized a seminar on “Yogavum Nalvalvum” was held on 20th July 2024, from 8.30 a.m. to 12.30 p.m., in collaboration with the Natural Wellness Society Pvt. Ltd at Navatkuli Madiya Maha Vidyalayam. This seminar was conducted for school students and teachers of Navatkuli Madiya Maha Vidyalayam, the programme highlighted the importance of yoga and wellness practices for a healthy lifestyle. A total of 55 participants joined the seminar.



2.2 Workshop on Anti-Microbial Resistance

The Sri Lankan Society for Microbiology, Jaffna Chapter, conducted a workshop on Anti-Microbial Resistance for A/L Biology teachers and school students in the Jaffna district from 9.00 a.m. to 12.00 on 6th December 2024 at Faculty of Graduate Studies, University of Jaffna. The staff members Dr. (Ms.) T.Thayalini, Dr. (Ms.) S.Sivagnanam, Dr. (Ms.) S. Krishna, Dr. (Ms.) V.M.Prasad & Dr.(Ms.) R.Mirraaj of Faculty of Siddha Medicine, assisted this workshop as members of the Sri Lankan Society for Microbiology. The session focused on creating awareness about the growing threat of antimicrobial resistance and emphasized preventive practices. Around 100 participants attended the workshop.

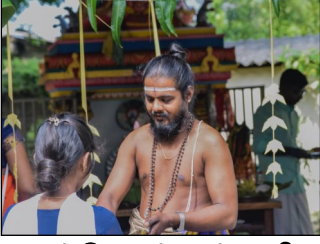
Later from 1.00 p.m to 5.00 p.m, a Theme Seminar on Microbiome was organized for Academics from the University of Jaffna and the University of Peradeniya. This seminar explored recent scientific findings on microbiomes and their significance in human health, offering deeper academic insights. A total of 50 Academics participated.



3. Activities by the Siddha Medical Students' Union (SMSU)

வாணி விழா 2024

யாழ்ப்பாணப் பல்கலைக்கழகத்தின் சித்த மருத்துவ பீடத்தில் விஜயதசமியை முன்னிட்டு 12.10.2024 அன்று விசேட பூஜை, ஏடு தொடக்கல், கோலப்போட்டி, மாலைகட்டுதல் போட்டி மற்றும் கலாச்சார நிகழ்வுகள் சிறப்பாக இடம்பெற்றன. இதற்கு முன் ஒன்பது நாட்கள் நவராத்திரி பூஜைகள் முறையே பீடாதிபதி, கல்வி சார் உத்தியோகத்தர்கள், கல்வி சாரா உத்தியோகத்தர்கள், முதலாம் வருட, இரண்டாம் வருட, மூன்றாம் வருட, நான்காம் வருட மற்றும் ஐந்தாம் வருட மாணவர்களால் கொண்டாடப்பட்டது.



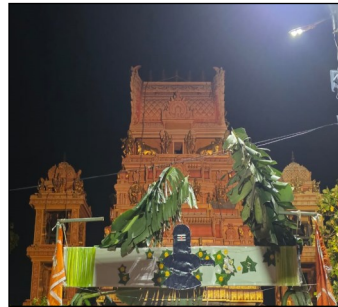
தைப்பொங்கல் விழா 2025

தைப்பொங்கல் தினத்தை முன்னிட்டு தைப்பொங்கல் விழா நிகழ்வுகளான பொங்கும் நிகழ்வுகள், உறியடி நிகழ்வுகள் 08.02.2025 அன்று சித்த மருத்துவ பீடத்தில் இடம்பெற்றது.



சிவராத்திரி விழா 2025

சிவராத்திரி தினத்தை முன்னிட்டு யாழ்ப்பாணப் பல்கலைக்கழக பரமேஸ்வரன் ஆலயத்தில் சித்த மருத்துவ பீடத்தின் பூஜைகள் 26.02.2025 அன்று இடம்பெற்றது.



இப்தார் விழா 2025

05.03.2025 அன்று புதன்கிழமை அன்று இப்தார் நிகழ்வுகள் சித்த மருத்துவ பீடத்தின் கேட்போர் கூடத்தில் இடம்பெற்றன.



பங்குனித் திங்கள் 2025

மட்டுவில் பன்றித்தலைச்சி அம்மன் கோயிலில் இறுதி பங்குனித்திங்கள் வழிபாடுகள் ஏப்ரல் 11 திங்கட்கிழமை அன்று காலை இடம்பெற்றன.



இரத்த தான நிகழ்வு 2025

சித்தமருத்துவ பீடத்தில் மறைந்த சகோதரி செல்வி.இ.ஷயஹரியின் நினைவாக மாணவர் ஒன்றியத்தினால் இரத்த தான நிகழ்வு 03.03.06.2025 அன்று ஒழுங்குபடுத்தப்பட்டிருந்தது. யாழ் போதனா வைத்திய சாலையின் இரத்த தான வங்கியில் நிலவிய குருதி தட்டுப்பாடு காரணமாக ஒன்றியத்தின் ஏற்பாட்டில் இரத்த தான முகாம் இடம்பெற்றது.



சித்தமருத்துவ வாரம் 2025

சித்த மருத்துவ மாணவர் ஒன்றியத்தால் சித்தமருத்துவ வாரம் இடம்பெற்றது. சித்தமருத்துவ அலகில் அணிகளுக்கிடையில் ஆண் பெண் இருபாலருக்குமிடையிலான சதுரங்கம் கரம் போட்டிகள் சிறப்பான முறையில் நடாத்தப்பட்டன. Badminton, Table tennis, Cricket என்பன யாழ்ப்பாணப் பல்கலைக்கழக உள்ளக விளையாட்டு அரங்கில் இடம்பெற்றது. தடகள விளையாட்டுகள் யாழ்ப்பாணப் பல்கலைக்கழக மைதானத்தில் நடைபெற்றது.



Safety and Effectiveness of Liv.52[®] DS in Varied Hepatic Disorders: An Open-Label, Multicenter, Phase 4 Study



An excerpt of a clinical study conducted by Shivnitwar SK et al that was published in *Cureus: Journal of Medical Science* has been featured here.

Abstract

The hepatoprotective function of the polyherbal formulation Liv.52 DS in chronic liver diseases (CLDs) is well recognized in published literature. The objective of this open-label, phase 4 study was to further strengthen and validate the safety and effectiveness of Liv.52 DS using a large patient pool in a real-world scenario and provide scientific data on symptomatic improvement and supportive treatment in liver function with improvement in quality of life.

Adult patients of either sex with one or more clinical symptoms such as fatigue, nausea, anorexia, abdominal pain or discomfort, muscle cramps, jaundice, or any other signs and symptoms with a history suggestive of mild-to-moderate hepatic disorders received 2 Liv.52 DS tablets, BID, for 12 weeks, orally. Of the 1,000 enrolled patients, 962 completed the study. A majority of the patients treated with Liv.52 DS showed statistically significant improvement in various clinical signs and symptoms, liver function test parameters, and all the components of the CLD questionnaire scores from baseline to 12 weeks.

The study demonstrated that Liv.52 DS is a hepatoprotective and well-tolerated by the study population for 12 weeks. No significant or new safety signals emerged from this study.

Aim

To evaluate the safety and effectiveness of Liv.52 DS tablets in various hepatic disorders using a large patient pool and to provide scientific data on symptomatic improvement and supportive treatment in liver functions along with improvement in quality of life (QoL).

Materials and Methods

Inclusion criteria

This open-label, multicenter, phase 4 study enrolled 1,000 patients (aged > 18 y) of either sex, with one or more clinical symptoms of liver disorders such as fatigue, nausea, anorexia, abdominal pain or discomfort, muscle cramps, or jaundice, and patients with a history suggestive of mild-to-moderate hepatic disorders such as alcoholic liver disease (ALD) (wherein a history of persistent alcohol intake and

liver function test [LFT] parameters suggest a liver disease); nonalcoholic fatty liver disease (NAFLD) (wherein the patient's history is suggestive of impaired metabolic function, and the final diagnosis was made through exclusion); drug-induced hepatotoxicity (DIH) (wherein the patients have a specific history of drug intake attributed to liver injury, or they are on antitubercular and antiretroviral therapies); or hepatitis (wherein patients presented with elevated LFTs, suggestive of hepatitis).

Exclusion criteria

Patients suffering from severe hepatic conditions including hepatocellular carcinoma, hepatitis B, hepatitis C, portal hypertension, splenomegaly, hepatic encephalopathy, swelling in/bleeding from the hepatic veins, fluid accumulation in the abdomen, nonalcoholic steatohepatitis with cirrhosis, as

well as those undergoing active treatment for alcohol withdrawal syndrome, those undergoing treatment for chronic liver diseases (CLDs), or those in a state of confusion were excluded from the study. Patients with normal LFTs, with highly elevated levels of alanine aminotransferase (ALT) and aspartate aminotransferase (AST), with compromised hematologic parameters (total white blood cells < 3,000 cells/mm³, absolute neutrophils < 1,500 cells/mm³, and platelets < 100,000/mm³), with serum creatinine > 2 mg/dL, or with creatinine clearance < 60 mL/min at screening were also excluded from the study. The study also excluded pregnant or lactating women.

Treatment

Eligible patients were treated with 2 tablets of Liv.52 DS, orally, BID, for 12 weeks, and this was considered the end of the study (EOS).

Assessments

Safety evaluations included monitoring of adverse events (AEs) throughout the study. Clinical laboratory data on hematological and biochemical parameters, physical examinations, and vital signs were evaluated. Efficacy evaluation included changes in LFT parameters (ie, ALT, AST, bilirubin, and alkaline phosphatase [ALP]) from baseline to EOS. Changes in clinical signs and symptoms (ie, fatigue, nausea, anorexia, abdominal pain or discomfort, muscle cramps, jaundice, and any other symptoms related to mild-to-moderate hepatic disorder) were also evaluated in all the patients. Patient-reported QoL assessments were performed using the CLD questionnaire (CLDQ) comprising abdominal symptoms, fatigue, systemic symptoms, activity, emotional function, and worry.

Statistical analyses

Safety was analyzed for the “safety analysis” set comprising patients who were allocated to the treatment and who received at least 1 dose of the study drug. Efficacy parameters were analyzed using the “per protocol analysis” set comprising patients who completed the study as per the protocol. Continuous data were analyzed using paired

t test or Wilcoxon signed rank test, wherever appropriate, for comparing pre- and post-treatment data. Categorical data such as the shift from abnormal to normal and overall improvement were analyzed using McNemar’s test and *Z* test. All statistical tests and confidence intervals were 2-sided, unless otherwise stated, *P* < .05 was considered significant.

Results

Of the 1,000 enrolled patients, 962 (96%) completed the study. A significant improvement (*P* < .0001) was observed in ALP (78.59%), serum bilirubin (70.32%), ALT (81.21%), and AST (75.36%) levels from the baseline to EOS (Figure 1).

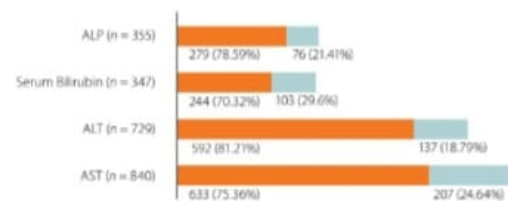


Figure 1. Improvement in Liver Function Parameters From the Baseline to the End of the Study

ALP, alkaline phosphatase; ALT, alanine aminotransferase; AST, aspartate aminotransferase.

LFT in patients with various hepatic disorders

The overall reduction in AST, ALT, and ALP are presented in Figure 2A. In patients with ALD, the AST, ALT, bilirubin, and ALP levels significantly reduced by 52.88%, 59.93%, 26.01%, and 27.86% (all *P* < .0001), respectively, by EOS (Figure 2B). In patients with NAFLD, the AST, ALT, and ALP levels reduced by 52.22%, 58.05%, and 28.97% (all *P* < .0001), respectively, by EOS (Figure 2C). In patients with NAFLD and diabetes, the AST, ALT, bilirubin, and ALP levels reduced by 38.3% (*P* < .0277), 46.5% (*P* < .0091), 16.7%, and 15.3%, respectively, by EOS (Figure 2D).

In patients with DIH, the AST, ALT, bilirubin, and ALP levels reduced by 58.61%, 72.09%, 47.38%, and 45.31%, respectively, by EOS (Figure 2E). In the subgroup analysis performed on patients who had DIH due to antitubercular

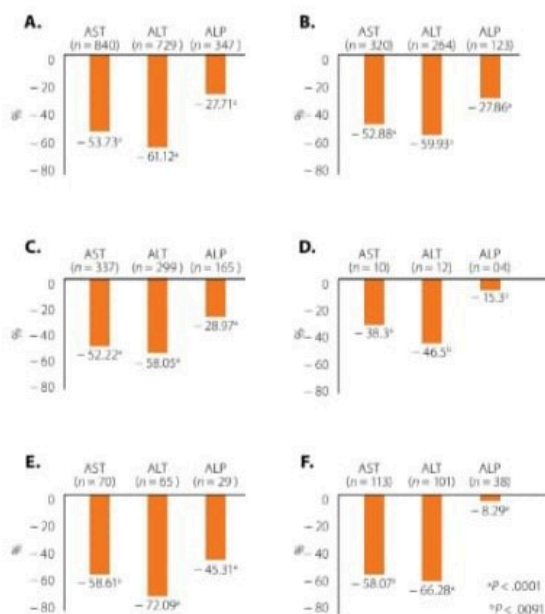


Figure 2. Average Percentage Reduction in LFT Values for Patients who had Abnormal Values at Baseline: (A) Overall Patient Population; (B) Patients With ALD; (C) Patients With NAFLD; (D) Patients With NAFLD and Diabetes; (E) Patients With DIH; and (F) Patients With Hepatitis

ALD, alcoholic liver disease; ALP, alkaline phosphatase; ALT, alanine aminotransferase; AST, aspartate aminotransferase; DIH, drug-induced hepatotoxicity; LFT, liver function test; NAFLD, nonalcoholic fatty liver disease.

treatment, there was a 70% reduction in the ALT level within 2 to 3 weeks ($P < .0001$) of the treatment. In patients with hepatitis, the AST, ALT, bilirubin, and ALP levels reduced by 58.07%, 66.28%, 17.5%, and 8.29% (all $P < .0001$), respectively, by EOS (Figure 2F).

Overall, 49% of the patients with fatigue, tiredness, or weakness; 79.3% of the patients with nausea; 76% of the patients with abdominal pain; and 71% of the patients with muscle cramps at baseline became symptom-free by EOS. Complete relief of anorexia symptoms was seen in 78.23% of the patients by EOS. Of the remaining patients, 5.6% showed a reduction in the grade of anorexia—from grade 2 or 3 to grade 1 by EOS. Also, a statistically significant improvement ($P < .005$) was seen in all the components of the CLDQ scores from the baseline to EOS.

Only 3 patients experienced AEs related to Liv.52 DS tablet or adverse drug reactions such as mild abdominal pain (0.2%) and moderate acidity (0.1%). There were no significant changes or worsening in hematologic parameters, creatinine levels, or vital signs during the study.

Conclusion

Treatment with Liv.52 DS tablets for 12 weeks led to statistically significant improvements in clinical signs and symptoms, liver enzyme levels, and health-related QoL scores across different patient subgroups. With a favorable safety profile, as demonstrated in this study, Liv.52 DS tablet emerges as a promising complementary or alternative therapeutic option for managing CLD of mild-to-moderate severity. Overall, this large, multicenter, phase 4 study provides real-world evidence that the polyherbal formulation, Liv.52 DS tablet, is an effective and safe option for patients with various hepatic disorders including ALD, NAFLD, DIH, and viral hepatitis.



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