

INA-RESPOND Study Sites

- | | |
|---|--|
| 1 RSUP Dr. Hasan Sadikin, Bandung | 12 RSUD Dr. H. Moch. Ansari Saleh, Banjarmasin |
| 2 RSUP Prof. Dr. I.G.N.G. Ngoerah, Denpasar | 13 RS Umum St. Carolus, Jakarta |
| 3 RSUPN Dr. Cipto Mangunkusumo, Jakarta | 14 RS Umum Budi Kemulian, Batam |
| 4 RSPI Prof. Dr. Sulianti Saroso, Jakarta | 15 RSUD Abdoel Wahab Sjahranie, Samarinda |
| 5 RSUP Dr. Wahidin Sudirohusodo, Makassar | 16 RSUD Dr. Zainoel Abidin, Aceh |
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THANK YOU

INA-RESPOND NETWORK & PARTNERS

INA-RESPOND SCIENCE TEAM, CLINICAL RESEARCH SITE SPECIALISTS, SITE RESEARCH TEAM, CLINICAL RESEARCH ASSOCIATES TEAM, DATA MANAGEMENT TEAM, REFERENCE LABORATORY TEAM, FINANCE AND ADMINISTRATION TEAM, DIGITAL PLATFORM DEVELOPMENT TEAM, US NIH, NIAID, LEIDOS, INA-RESPOND STAKEHOLDERS.

INA-RESPOND SECRETARIAT

BADAN KEBIJAKAN PEMBANGUNAN KESEHATAN,
GEDUNG 6, LANTAI 3.
JL. PERCETAKAN NEGARA NO.29,
JAKARTA 10560

02

OPERATIONS & ACTIVITIES

05

SCIENCE CORNER

08

SPORTS & LIFESTYLE

12

ANNOUNCEMENT

OPERATIONS & ACTIVITIES

SITE PREPARATION: SAV & SPV

By: INA-RESPOND CRSS

INTRODUCTION

High-quality clinical research must be conducted in accordance with Good Clinical Practice (GCP) to ensure scientific integrity, ethical standards, and the safety of study participants. Adherence to GCP not only strengthens the credibility of research findings but also builds trust in the healthcare systems that support such studies.

As part of a collaboration between INA-RESPOND and the Clinical Research Unit (CRU) at RSPI Prof. Dr. Sulianti Saroso, a clinical research operations training program is held to enhance local capacity in conducting GCP-compliant studies. The training, held every Monday starting March 10, 2025, covers key areas including study preparation, implementation, monitoring, and data management.

SITE PREPARATION ACTIVITIES

The clinical study process begins with the Site Assessment Visit (SAV) followed by Site Preparation Visit (SPV), Site Activation, Study Ongoing, and Study Closure. These are essential steps to ensure that the study sites are fully prepared for the study implementation.



Figure 1. Steps in the Clinical Study Process.

The first session focused on the critical early phases of study setup: SAV and SPV. These steps are essential to ensure that sites are adequately prepared and aligned with both protocol requirements and ethical standards. This article summarizes the training session, and the key materials presented to support consistent, high-quality study implementation across sites.

Site Assessment Visit (SAV)

The SAV is a critical activity conducted to evaluate proposed new study sites. Its primary purpose is to ensure that investigators and facilities are selected according to Good Clinical Practice (GCP) standards and that they meet the specific needs of the clinical trial protocol as well as INA-RESPOND's requirements for conducting the study.

An SAV may be scheduled once a study is assigned to INA-RESPOND, either through an on-site visit or via a phone interview, to assess the site's feasibility for participation. The SAV process is led by the Clinical Research Site Specialist (CRSS), in collaboration with the protocol team and other relevant staff members.

- **Prior** to the visit, several preparations are undertaken, including the development of a Non-Disclosure Agreement (NDA) and the SAV Form. Site personnel's qualifications and experience are assessed through a review of their Curriculum Vitae (CVs) and GCP training documentation. Additional evaluations include the site's commitment to conducting clinical studies, the availability and

quality of facilities, access to the appropriate study population, and compliance with local regulations and requirements.

The assessment visit is scheduled with the Principal Investigator (PI), and a SAV confirmation letter is prepared. The SAV Form is then sent to the investigator and site team, along with instructions for its completion and submission ahead of the scheduled visit.

- During the visit, the team provides an introduction and overview of the study. Using the SAV Checklist, the assessment team reviews and discusses key aspects with the site team, verifies essential documents, and records the outcomes of the assessment. If feasible, a tour of the site's facilities and study-related rooms is also conducted to ensure that the infrastructure meets the study's operational needs.

- Following the SAV, a follow-up letter is prepared to summarize the findings. Based on the assessment results, a decision is made regarding the site's eligibility for inclusion in the study, which leads to the selection of final study sites.

If all requirements are met and the site is deemed capable of conducting the study, preparations will proceed for the next step—the SPV.

Site Preparation Visit (SPV)

The SPV is a critical activity designed to ensure that the PI and the study team at the selected site fully understand the study requirements from initiation through to completion. The SPV is conducted after the study has been approved by Institutional Review Board (IRB) and/or regulatory and once the contract is finalized. It is led by the protocol investigator and supported by other protocol team members, the secretariat, sponsor representatives, and additional staff as needed, all prior to the site's official activation. The SPV may be conducted either onsite or remotely through webinars or teleconferences. In some cases, the SPV may be combined with the Site Initiation Visit (SIV).

- Prior to the visit, the study protocol, Manual of Procedures (MOP), and supporting documents are distributed to the site team for review to ensure they are well-prepared. All logistical arrangements should also be in place ahead of the visit.

Several essential documents and materials must be prepared, including:

- The Study Site Preparation Checklist is a form completed by the CRSS to review key aspects related to the site's readiness for study implementation. It covers various components including the research team involved, available facilities, contracts, regulatory requirements, essential documents, site procedures and management, laboratory facilities, training, and logistics. This document is signed by both the site PI and CRSS who completed the form.
- The SPV confirmation letter and visit agenda.
- The presentation slides to be used during the visit.
- Study essential documents, including the Site Regulatory Binder (SRB)/Investigator Site File (ISF) and Trial Master File (TMF), along with their contents such as Standard Operating Procedures (SOP) templates, subject forms, and other materials according to the SRB Table of Contents.
- Authority access to applications (eCRF/ electronic Case Report Form, eSRB) and the Access Authorization Form.
- The SRB/ISF, Investigational Product (IP), office and laboratory supplies, and study equipment are distributed to the site.

- During the SPV, the study team provides comprehensive training and facilitates discussions covering GCP, the study protocol, MOP, laboratory manual, financial procedures, and a review of site-specific SOPs. Several key documents are reviewed and completed during the visit, including:

- SPV attendance list
- Site visit log
- Authorized and Signature Delegation Log

- Investigator of Record Agreement
- Site-specific SOPs

Additionally, the SRB, subject folders (including Source Document Worksheets and Informed Consent Forms), and CRF folders (including subject data collection schedules and CRFs) are checked for completeness and accuracy. The team also verifies the receipt of office and laboratory supplies, study equipment, and the IP. The Study Site Preparation Checklist is completed, and any pending items are flagged for follow-up.

- **After** the SPV, any outstanding documents or missing requirements are addressed internally, and follow-up actions are coordinated with the site. The SPV Checklist is updated, and a follow-up letter is prepared. In cases where issues remain unresolved, such as pending IP distribution, the checklist must be updated regularly until all requirements are met. The electronic SRB (eSRB) (if applicable) is also reviewed regularly to ensure the latest documents have been uploaded.

If the SPV is combined with the SIV, the Clinical Research Associate (CRA) is responsible for completing the SIV Report and sending the finalized Study Site Preparation Checklist to the site.

Once the SPV Checklist is finalized and signed by the site PI, it indicates that the site is ready to implement the study protocol and will be proceed to the next preparation step—Site Activation.

By focusing on the critical early phases of clinical research—such as the SAV and SPV— is essential to ensure that study sites are fully equipped to conduct high-quality, GCP-compliant trials. These structured processes not only support the readiness of study teams and infrastructure but also help establish consistency and compliance across multiple sites.



(Source: Clinical Research Memes Facebook Group)

Between Promises and Practice

We've all been there. At the Site Preparation Visit, everything looks polished—documentation lined up, SOPs printed, and site staff confidently pledging top-tier quality. But once the study kicks off, reality hits hard. Protocol deviations, incomplete logs, and a pile of CRFs looking like a battlefield.

This lighthearted meme captures that all-too-familiar shift from “we’ve got this” to “what happened?”. **It's a reminder that maintaining quality isn't just about strong starts, but consistent follow-through.** Let's laugh—but also reflect—on how we can better support sites to stay more eagle than pigeon throughout the study life cycle.

Could a Tailor-Made HIV Vaccine be Indonesia's Breakthrough?

By: Amalia Rani Setyawati, Cintya Naya Danastri, Ivana Yulian

What's this about?

HIV/AIDS continues to affect millions of people worldwide, and although antiretroviral therapy (ART) has transformed the disease into a manageable chronic condition, access to treatment remains uneven, especially in low- and middle-income countries like Indonesia. CRF01_AE is a frequent HIV subtype in Indonesia. Patients infected with CRF01_AE generally have faster disease progression and lower survival rates. Recent studies have also shown that CRF01_AE is associated with distinct clinical and immunological features, necessitating tailored approaches. Given this context, a low-cost, locally tailored vaccine would offer a powerful alternative.

In commemoration of HIV Vaccine Awareness Day on May 18, this edition highlights recent progress in HIV vaccine research, including an innovative approach developed specifically for Indonesia. A study by Khairunisa et al. introduced a multi-epitope vaccine (MEV) designed specifically for the CRF01_AE subtype using bioinformatics tools. Epitope-based vaccines rely on carefully selected viral fragments (antigens) that can effectively stimulate the immune system. This study aimed to reduce HIV-related morbidity and mortality in Indonesia by creating a vaccine that fits the genetic profile of the local population.

How was the study conducted?

Khairunisa et al. began by analyzing over 900 genomic sequences of the HIV-1 CRF01_AE subtype to evaluate the mutation rates of various viral proteins. They found that the Pol protein had the lowest mutation rate, making it a stable and promising vaccine target. Although the Env protein showed a

higher mutation rate, it was also selected due to its essential role in viral entry and immune recognition. From these two proteins, the researchers identified nine optimal epitopes—five for cytotoxic T cells (CTLs), four for helper T cells (HTLs), and one B cell epitope capable of inducing broadly neutralizing antibodies (bnAbs). Each epitope was evaluated for physicochemical properties such as solubility and structural stability. The selected epitopes were assembled into a multi-epitope vaccine construct with a modeled molecular structure and 3D conformation. Researchers then simulated the vaccine's interaction with immune components using computational tools.

What did the study find?

The study identified the critical epitopes for a subtype of HIV-1, which is prevalent in Indonesia and Southeast Asia. The structure of the designed vaccine is shown in Figure 1. The selected epitopes demonstrated high antigenicity and immunogenicity scores, indicating their potential to elicit robust humoral and cellular immune responses, essential for long-lasting immune protection. The final MEV construct consisted of 272 amino acids and was predicted to be non-allergenic, with high thermal stability and strong interaction capabilities.

The fragment antigen-binding (FAB) region is the part of an antibody that specifically binds to antigens. Molecular docking results between the MEV construct and the FAB region demonstrated strong and specific interactions, involving 10 hydrogen bonds at the binding interface (Figure 2). These hydrogen bonds, essential for stabilizing protein-protein interactions, underscored the MEV's potential to trigger robust and targeted immune responses.

es. While the FAB region exhibited notable structural stability, the MEV construct showed greater flexibility, likely facilitating adaptive binding. This combination of MEV flexibility and stable complex formation with the FAB region suggests a promising design for effective vaccine development.

Immunogenicity assessments of the MEV construct revealed a robust antigen-specific immune response over a 35-day simulation period. Antigen levels peaked within the first five days before declining, while antibody titers progressively increased, reaching a maximum around day 15.2. These patterns indicated early immune activation followed by a sustained humoral response, supporting the construct's potential efficacy. Cytokine profiling also showed a pronounced immunological response, further reinforcing the MEV's capacity to stimulate both arms of the immune system.

Why does this matter?

Researchers have struggled to develop HIV-1 vaccines that elicit antibodies capable of neutralizing the virus's diverse strains because of its extensive genetic diversity, high mutation rates, and rapid replication. This study presents a novel, Indonesia-specific vaccine strategy that addresses these obstacles by targeting the predominant CRF01_AE subtype.

Structural analysis of the MEV construct revealed high stability, solubility, and optimal exposure of antigenic components, all critical for effective immune recognition. This structural integrity is expected to be maintained during storage, transport, and administration, ensuring the vaccine's effectiveness in real-world conditions. Complementary molecular docking and molecular dynamics simulations confirmed strong, stable interactions between the MEV and the FAB. Furthermore, immunogenicity assessments demonstrated significant and sustained antibody responses and diverse cytokine profiles, reflecting both immediate and long-term immune activation.

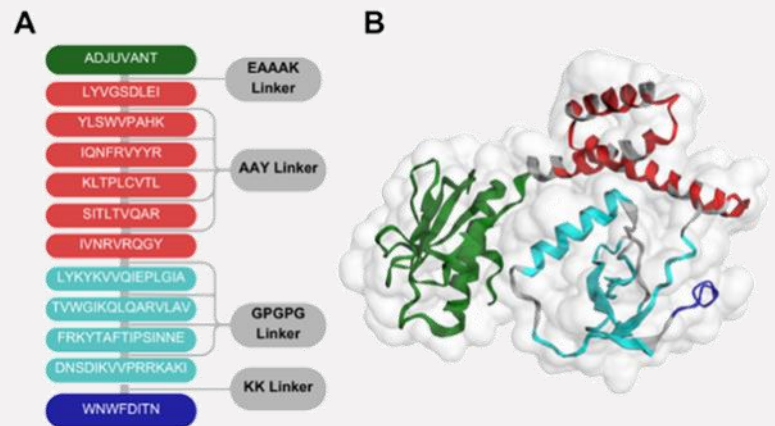


Figure 1. (A) Schematic representation of the MEV construct, showing the arrangement of epitopes, adjuvants, and linkers. (B) Three-dimensional structural model of the MEV construct, with colors corresponding to those in (A).

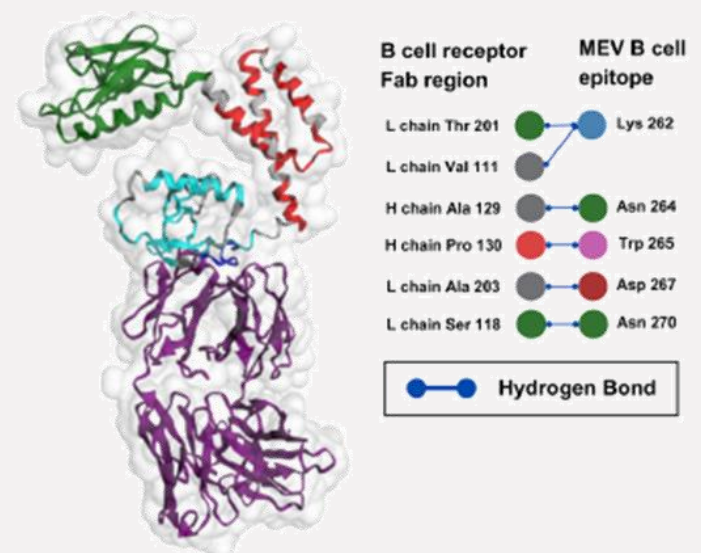


Figure 2. The binding involves ten hydrogen bonds between the B cell epitope of the construct and the FAB binding region. The MEV construct components are color-coded as in Figure 2.

Any limitations?

While the study presents promising findings, it was conducted entirely using computational (in silico) methods, meaning that none of the predictions have been validated through laboratory experiments, animal studies, or human clinical trials. As such, the success of the MEV depends on how well it performs in real biological conditions. However, translating in silico results into in vivo outcomes is complex. Preclinical testing often relies on animal models, particularly non-human primates and sim-

ian-human immunodeficiency virus models, due to their genetic and immunological similarities to humans. Yet even minor differences between these models and human biology have caused many vaccine candidates that showed promise in animals to fail in human trials.

Moreover, despite targeting conserved viral regions, HIV's high mutation rate and ability to evade immune responses remain significant hurdles. The risk of immune escape variants persists, even within a single subtype like CRF01_AE. Other biological challenges include the dynamic and diverse nature of HIV RNA, the virus's replication within host immune cells, the need for highly specific neutralizing antibody responses, and a limited understanding of immune system-virus interactions. These complexities highlight the need for ongoing genetic surveillance and comprehensive experimental validation before the vaccine can move forward.

What's next?

The next step is to test the vaccine design in real-world settings. Researchers need to start with lab experiments (in vitro) to check how well the epitopes bind to human immune proteins. Animal studies (in vivo) should be done to see if the vaccine can trigger an immune response and if it is safe. If those steps go well, the vaccine can move on to clinical trials in humans. It's also important to monitor if the virus changes over time and update the vaccine design if needed. Researchers might add more epitopes or focus on highly conserved regions targeted by known bnAbs to make it even more effective.

Indonesia has never conducted an HIV vaccine trial in humans, while Thailand has been a leading site for HIV vaccine research in Southeast Asia. The VAX003 trial (2006) tested a gp120-based vaccine in people who inject drugs but failed to prevent HIV infection and had no significant impact on viral load, CD4+ T-cell counts, or disease progression. The RV144 trial (2003–2009), involving over 16,000

participants, was the first to demonstrate partial protection, with 60% efficacy at 12 months, declining to 31.2% by 3.5 years. More recently, the APPROACH trial (2015–2019), conducted in multiple countries, including a small cohort in Thailand (~58 participants), evaluated a mosaic-based HIV vaccine regimen. The vaccine was safe and well tolerated, and all participants developed HIV-specific antibody responses and T-cell activation. Although the trial did not assess protection against infection, its findings supported the advancement to larger efficacy trials.

Finally, this study from Indonesia is a good starting point. If followed up with proper testing, it could lead to a vaccine designed for the specific HIV subtype in Indonesia. With continued research and collaboration, such efforts hold the potential to bring new hope in preventing HIV not only nationally, but also across the Southeast Asian region. Held annually on May 18, HIV Vaccine Awareness Day commemorates U.S. President Bill Clinton's 1997 declaration that "only a truly effective, preventive HIV vaccine can limit and eventually eliminate the threat of AIDS."

Article source:

Khairunisa SQ, Rachman BE, Nasronudin, Fahmi M, Dinana IA, Ito M. Designing a multi-epitope vaccine targeting the HIV-1 subtype CRF01_AE in Indonesia. *Computers in Biology and Medicine*. 2025 Mar;187:109758.

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SPORTS & LIFESTYLE

HEALING YOUR HEEL

Understanding Plantar Fasciitis: Current Concepts in Diagnosis, Management, and Prevention

By: Monica Surjanto

Heel pain is a common musculoskeletal complaint encountered in clinical practice, affecting individuals across a wide range of age groups and activity levels. Among the various causes of heel pain, plantar fasciitis stands out as the most frequent diagnosis. It involves inflammation of the plantar fascia, a thick band of connective tissue that runs across the bottom of the foot and connects the heel bone to the toes. The condition typically causes stabbing pain that usually occurs with the first steps in the morning, which may decrease with movement but can return after long periods of standing or after rising from sitting. The condition is particularly prevalent among athletes, individuals with biomechanical foot abnormalities, and those exposed to prolonged standing or repetitive stress. Given its high incidence and the potential for chronicity if not appropriately managed, understanding the etiology, risk factors, and effective management strategies of plantar fasciitis is essential for healthcare professionals aiming to provide optimal patient care.

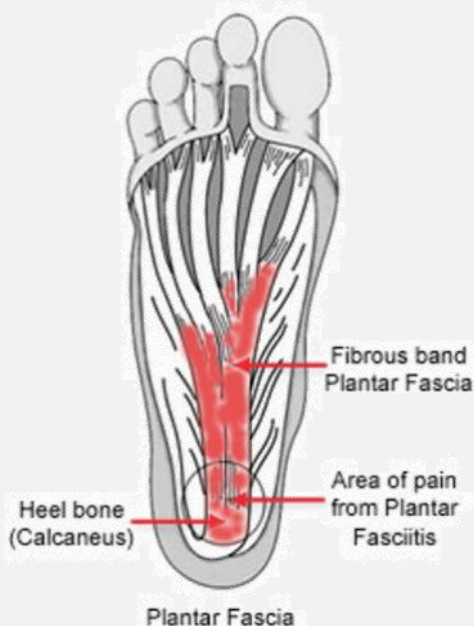


Figure 1.
Anatomy of the foot.

Risk Factors

Several factors may increase the risk of developing plantar fasciitis, including:

- **Age:** Plantar fasciitis is most common between the ages of 40 and 60.
- **Certain types of exercise:** Activities that place a lot of stress on the heel and attached tissue, such as long-distance running, ballet dancing, and aerobic dance, can contribute to early onset.
- **Foot mechanics:** Flat feet, a high arch, or even an abnormal walking pattern can affect the way weight is distributed while standing and put added stress on the plantar fascia.

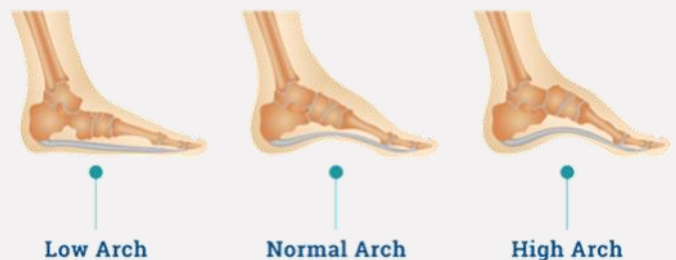


Figure 2. Arch types.

- **Obesity:** Excess weight puts extra stress on the plantar fascia.
- **Occupational risks:** Factory workers, teachers, and others who spend most of their work hours walking or standing on hard surfaces are at higher risk.

Etiology

Plantar fasciitis is primarily caused by repetitive strain injury to the ligament of the sole of the foot. Such strain injury can be from excessive running or walking, inadequate footwear, jumping injury from landing, or even from certain underlying diseases such as reactive arthritis.

The inflammation and micro-tearing of the fascia occur when there is too much pressure on the foot, leading to damage and pain. Over time, this leads to thickening and degenerative changes of the fascia, not just acute inflammation, which is why some experts refer to the condition as "plantar fasciosis."

Key etiological factors include:

- **Mechanical overload** (e.g., long periods of weight-bearing activities)
- **Degenerative changes** (similar to tendinosis rather than a purely inflammatory process)
- **Anatomical abnormalities** (e.g., tight Achilles tendon or limited ankle dorsiflexion)
- **Intrinsic muscle weakness** of the foot

Management

Treatment for plantar fasciitis is usually conservative and focuses on reducing pain and inflammation, promoting healing, and correcting underlying biomechanical problems.

1. Conservative Management

- **Rest:** Reducing or modifying activities that make the condition worse.
- **Ice application:** Applying ice to the heel for 15–20 minutes several times a day can help reduce inflammation.
- **Stretching exercises:** Especially calf and plantar fascia-specific stretches.
- **Footwear modifications:** Using shoes with good arch support and a cushioned sole.
- **Orthotics:** Custom or over-the-counter shoe inserts to support the arch and distribute pressure more evenly.
- **Medications:** Nonsteroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen can relieve pain and inflammation.
- **Exercise Therapy:** A physical therapist may instruct on exercises to stretch the plantar fascia and Achilles tendon and to strengthen lower leg muscles, which stabilize the ankle and heel.



Figure 3. Manual plantar fascia stretch with cross-friction massage. Stretch and massage before taking first steps for 1 minute 3 times with 30 seconds of rest in between.



Figure 4. Calf and arch stretch using a towel.

Consider keeping the towel near the bedside and performing before going to sleep and before taking first steps in the morning. Pull back on foot for 30 seconds 3 times with 30 seconds of rest in between.



Figure 5. Roll plantar fascia with can or ball.

Consider keeping at the bedside and performing before going to sleep and before taking first steps in the morning. Roll plantar fascia for 1 minute 3 times with 30 seconds of rest in between.

- **Night Splints:** Wearing a splint that holds the foot in a dorsiflexed position overnight can stretch the plantar fascia and Achilles tendon during sleep.



Figure 6. Night splints.

2. Advanced Therapies

If conservative treatments fail:

- **Corticosteroid injections:** To reduce inflammation (used cautiously due to the risk of plantar fascia rupture).
- **Extracorporeal shock wave therapy (ESWT):** A non-invasive technique that uses sound waves to stimulate healing.
- **Platelet-rich plasma (PRP) injections:** Emerging treatment options to promote tissue regeneration.
- **Surgical Intervention:** Surgery is rarely needed and is considered only after 6–12 months of ineffective conservative therapy. Procedures typically involve detaching the plantar fascia from the heel bone (partial plantar fasciotomy) to relieve tension.

Prevention

Preventing plantar fasciitis involves measures that reduce strain on the plantar fascia, including:

- **Wearing appropriate footwear:** Choose shoes with proper arch support and heel cushioning.
- **Maintaining a healthy weight:** To reduce stress on the feet.
- **Regular stretching:** Stretching the calves, Achilles tendons, and plantar fascia to maintain flexi-

bility.

- **Gradual progression in activities:** Especially when starting new exercise routines or sports.
- **Strength training:** Building up intrinsic foot muscles to support the arch.
- **Avoid walking barefoot on hard surfaces:** Especially first thing in the morning.

Preventative measures are particularly important for individuals with a history of foot problems or those engaging in high-impact activities.

Conclusion

Plantar fasciitis continues to be the most prevalent cause of heel pain encountered in both general and sports medicine. It affects a broad population—from sedentary individuals to athletes—and can significantly hinder mobility, work productivity, and overall quality of life when not promptly addressed. Its etiology is multifactorial, with key contributors including age-related changes, biomechanical foot abnormalities, excessive body weight, repetitive high-impact activities, and prolonged standing on hard surfaces. These factors contribute not only to inflammation but also to chronic degenerative changes within the plantar fascia, reinforcing the evolving view of the condition as "plantar fasciosis."

A comprehensive management plan involves addressing the root mechanical causes and providing symptom relief. Conservative treatments remain the cornerstone of care and include rest, ice application, stretching exercises, use of proper footwear with adequate arch support, orthotic devices, and physical therapy to improve strength and flexibility. These interventions are often sufficient to alleviate symptoms in the majority of patients. For those who do not respond to initial treatments, more advanced options such as corticosteroid injections, extracorporeal shock wave therapy, or platelet-rich plasma (PRP) injections may be considered. Surgical intervention is rarely necessary and is generally reserved for chronic, treatment-resistant cases after at least six to twelve months of conservative management.

Equally important is prevention, which emphasizes proactive strategies such as maintaining a healthy body weight, wearing supportive shoes, stretching regularly (especially before getting out of bed), and gradually increasing activity levels to avoid overloading the plantar fascia. Strengthening the intrinsic muscles of the foot also plays a crucial role in long-term foot health.

Ultimately, a thorough understanding of the pathophysiology, risk factors, and evidence-based treatment options for plantar fasciitis allows healthcare professionals to tailor individualized care plans. Such an approach not only enhances treatment outcomes but also empowers patients to actively participate in their recovery and prevent recurrence, leading to better functional performance and improved quality of life.

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KEEP YOUR HEEL HEALTHY



Risk Factors



Treatment



Prevention

For illustration purposes only.

ANNOUNCEMENT

FAREWELL TO OUR CO-WORKERS: CHANDRA & RESTU

By: INA-RESPOND Secretariat



Chandra Ilham El Anwary Junior
Data Entry Specialist
2021 – 2025

Chandra Ilham

It's never easy to say goodbye to someone as creative, fun, and dedicated as Chandra Ilham El Anwary Junior—our awesome Data Entry Specialist from Jan 2021 to May 2025, and also the man behind our digital platform contents from Mar 2024 to May 2025.

From keeping our databases sharp and clean, making sure every CRF was in top shape, to helping the data team with trackers, datasets, and everything in between—Chandra did it all with heart, humor, and a whole lot of talent. His attention to detail (and movie recommendations!) made our workdays brighter and our data stronger, especially in the InVITE and PROACTIVE studies.

We'll definitely miss your creative spark and positive energy around the team. Wishing you all the best in your next adventure, Chandra—go shine wherever you go!

Restu Amalia Mukti

We would like to extend our heartfelt appreciation to Restu Amalia Mukti for her dedication and contributions during her time as a Clinical Research Site Specialist staff at INA-RESPOND from April 2022 to May 2025.

Restu played a vital role in Site Management and Regulatory Affairs, supporting several key studies including D2EFT, InVITE, ORCHID, and PROACTIVE. She was not only reliable and meticulous in her work but also known for her helpful nature and eagerness to learn and grow. Her kindness, team spirit, and enthusiasm have truly enriched the INA-RESPOND Secretariat.

As she moves forward, we wish Restu every success in her professional path—and send our best wishes for her personal journey ahead as well. May everything go smoothly as she looks forward to a new and exciting chapter.

Thank you, Restu, for being such a valuable part of the team. You will be missed!



Restu Amalia Mukti
Clinical Research Site Specialist
2022 – 2025



INA-RESPOND Newsletter

The Indonesia Research Partnership on Infectious Disease newsletter is an internal bulletin of INA-RESPOND research network intended to disseminate information related to the network's studies, activities, and interests to all members of the network as well as its sponsors and related parties.

The INA-RESPOND newsletter welcomes all network members and stakeholders to contribute by submitting articles related to the network's studies and interests. Send your articles or subscribe to our latest newsletter

by sending an email to
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