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Immunogenicity of an intradermal live attenuated tetravalent dengue vaccine among healthy volunteers: A pilot study

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1. Thai title

การศึกษานำร่องการทดสอบภูมิคุ้มกันต่อเชื้อไวรัสเดงกี่หลังได้รับวัคซีนไข้เลือดออกเชื้อเป็นอ่อนฤทธิ์ชนิดสี่สายพันธ์เข้าผิวหนังในกลุ่มอาสาสมัครสุขภาพดี

2. English title

Immunogenicity of an intradermal live attenuated tetravalent dengue vaccine among healthy volunteers: A pilot study

3. Keywords

English: Dengue, Intradermal vaccination, Immunogenicity, T cell response, Tetravalent dengue vaccine

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5. Details of proposal

5.1 Background

Dengue fever, caused by the dengue virus (DENV), represents a significant global health challenge, particularly in tropical and subtropical regions. This disease affects millions of individuals annually, resulting in severe morbidity and a substantial economic burden. Advanced age is a significant risk factor for increased severity and mortality associated with this condition[1], predicting an escalating impact in the future. In the absence of specific antiviral treatments, the development and implementation of effective vaccination strategies are crucial in mitigating the impact of dengue fever.

Qdenga, a live attenuated tetravalent dengue vaccine traditionally administered subcutaneously, has shown promising results in conferring immunity against all four dengue serotypes[2], this one also not need to check for previous infection as concerning of enhancing antibody as the previous Dengvaxia vaccine, promoting more opportunity.

5.2 Study setting background

Intradermal vaccination is an established method known to enhance immunogenicity by targeting the rich network of antigen presenting cells present in the dermis[3], WHO have done a literature review in 2009 for studies about intradermal injection proposed that a fractional ID dose can induced adequate immune responses in healthy persons for variable type of vaccines[4], including those for rabies, yellow fever, poliomyelitis, seasonal influenza and there also be more others recent studies focusing on the COVID-19 vaccination[5-7] as vaccine inequity remains a challenge across the globe.

5.3 Rationale

As in the setting of low- to middle-income countries, to demonstrating that lower doses of vaccine via intradermal route can still elicit robust immune responses, thereby lowering the overall cost of vaccination might be particularly meaningful ,with possible extra benefit of experiencing fewer side effects or risk of allergy[5, 8]. This study goal is to explores the potential of intradermal administration of Qdenga, hypothesizing that a lower dose via this route could achieve adequate immunogenicity compared to the standard subcutaneous administration, thus offering a cost-effective alternative particularly in low-resource settings where dengue is most prevalent.

5.4 Objectives

Primary Objectives

1. To evaluate the antibody response to dengue virus following administration of the second dose of Qdenga™ via the intradermal route.

2. To evaluate the T-cell response (CD4 and CD8) to dengue virus following administration of the second dose of Qdenga™ via the intradermal route.

Secondary Objective

1. To assess the safety and reactogenicity of intradermal administration of Qdenga.

5.5 Literature review

Dengue fever, attributable to the dengue virus, represents a substantial global health concern. The advent of vaccines such as Qdenga and Dengvaxia has demonstrated potential in conferring immunity

against all four serotypes of the dengue virus. However, given the higher prevalence of dengue fever in resource-limited tropical regions, it is crucial to explore cost-reduction strategies. Intradermal injection, a previously successful dose-sparing technique, offers one such strategy. Nonetheless, the efficacy of intradermal administration for the newly developed Qdenga vaccine remains uncertain and warrants further investigation.

Study on the immunogenicity of the Qdenga vaccine, given subcutaneously, have shown promising results. One randomized, placebo-controlled Phase 2 study[9] involving 148 participants aged 1.5 to 45 revealed seropositivity rates at month 36 of 97.3%, 98.7%, 88.0%, and 56.0% for DENV-1, -2, -3, and -4, respectively. Notably, seropositivity for DENV-4 varied significantly based on initial serostatus, with 89.5% in seropositive individuals compared to 21.6% in seronegative individuals. No vaccine-related serious adverse events (SAEs) were reported. The study demonstrated the persistence of neutralizing antibody titers and the Qdenga vaccine's tolerability over three years in both children and adults living in dengue-endemic regions.

A key concern with the dengue vaccine is the potential side effects, including transient vaccine viremia. After receiving the Qdenga vaccine, 49% of previously uninfected participants and 16% of those previously infected with dengue experienced vaccine viremia[10]. This viremia typically began in the second week post-vaccination, lasted an average of four days, and was associated with mild to moderate symptoms such as headache, joint pain, muscle pain, and rash in some subjects. During this period, dengue diagnostic tests may yield positive results, making it difficult to distinguish between vaccine viremia and wild-type dengue infection. A study on IgG, IgM, and nonstructural protein 1 (NS1) response profiles post-Qdenga vaccination indicated that IgM and IgG profiles within 30 days of vaccination were similar to those observed during natural dengue infections, though no NS1 antigen was detected[11]. As previously proposed that lower dose of vaccine might be associated with possible extra benefit of experiencing fewer side effects or risk of allergy[5, 8], intradermal reduced dosed sound compelling.

Qdenga vaccine was also called TAK-003/DENvax in previous study, it was based on a live-attenuated DENV-2 strain (PDK-53-V) in which the premembrane (prM) and envelope (E) genes have been replaced by the homologous genes from each one of the four DENV serotypes[12]. The recommendation for using the subcutaneous route in dengue vaccine administration is based on findings from certain Phase I studies. One such study assessed the safety and immunogenicity of a recombinant live attenuated tetravalent dengue vaccine (DENvax) in 96 flavivirus-naive healthy adults in Colombia. Participants in this study were randomized to receive either a high-dose formulation of DENvax or a placebo via

subcutaneous or intradermal injection. The study results indicated that both intradermal and subcutaneous routes elicited tetravalent dengue immune responses. However, the subcutaneous route was associated with a lower incidence of local adverse events compared to the intradermal route, although the difference was not statistically significant.[13].

Another study evaluated the safety and immunogenicity of an early low-dose tetravalent dengue vaccine candidate (LD-TDV), which uses an attenuated serotype 2 backbone, administered intradermally either with an injector device (PharmaJet) or a needle-syringe in 67 subjects. The findings indicated that the intradermal administration of LD-TDV was well tolerated, with no significant safety concerns, and induced an immune response against all four dengue serotypes[14]. The overall tetravalent seroconversion rates were 13.8% at Day 28 and 31.0% at Day 118, comparable to the previously reported 25% seroconversion rate for low-dose TDV given intradermally in 72 flavivirus-naive adults. Local reactions, such as induration (91.7% vs. 12.5%; $P < .0001$) and pruritus (50% vs. 8.3%; $P = .0034$), were more frequent following intradermal vaccination compared to subcutaneous administration. Most of these reactions were mild and resolved within one day[15].

This study aims to ensure the safety of vaccine recipients by comparing the administration of a second dose via the intradermal (ID) route after an initial subcutaneous (SC) dose with a control group receiving both doses subcutaneously (SC-SC). Previous research in Thailand on COVID-19 vaccines also evaluated the safety and immunogenicity of fractional (1/5th or 1/6th) doses of homologous ChAdOx1 or BNT162b2 administered intradermally following an initial intramuscular (IM) dose, demonstrating safety and immunogenicity[16]. Based on this, the study hypothesizes that intradermal administration of fractional doses of the Qdenga vaccine after an initial SC dose will be immunogenic and have acceptable systemic adverse effects, with potential utility as a booster in the future.

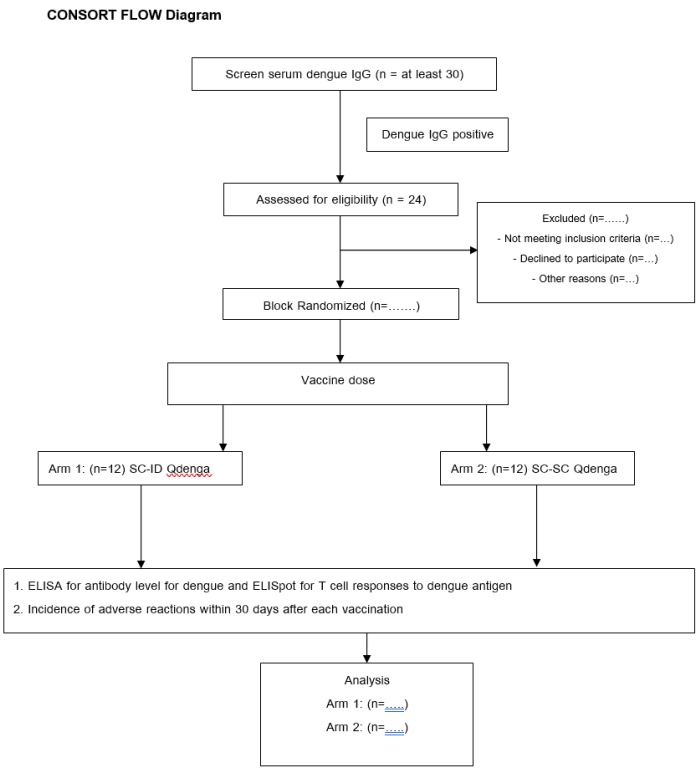
The potential of intradermal vaccination to maintain or enhance immunogenicity while reducing the required dose has been highlighted in several reviews[4, 17]. This method could lower costs and improve vaccine accessibility in low-resource settings. However, further research is needed, as no randomized studies have yet evaluated both humoral and cell-mediated immune responses to intradermal Qdenga vaccination.

5.6 Conceptual framework

A new dengue vaccine, Qdenga™, has recently become available in Thailand. As a live-attenuated vaccine, it does not require pre-vaccination serological screening for dengue immunity, unlike Dengvaxia™. However, access to Qdenga™ remains limited due to its high cost and the fact that it is not yet reimbursable for the general population. The vaccine is designed for subcutaneous administration and is given as a two-dose series, with the second dose administered three months after the first.

In theory, intradermal administration may elicit comparable immune responses while using a lower vaccine dose, owing to the high density of antigen-presenting cells in the dermal layer. Based on this rationale, investigators from multiple departments within the Faculty of Medicine have initiated a collaborative study to evaluate the immunogenicity and safety of intradermal Qdenga™ administration in healthy volunteers. Immune responses will be assessed at baseline, 30 days after the first dose, and 30 days after the second dose. All participants will receive the first dose subcutaneously as per standard practice, then be randomized to receive the second dose either subcutaneously or intradermally.

This study aims to enhance understanding of the immune response elicited by Qdenga™ given via different administration routes and to generate data that may inform future vaccine implementation strategies and potential dose-sparing approaches.



5.7 Research methodology

5.7.1 Study Design

Prospective observational study

5.7.2 Study Setting

Clinical research center, Prince of Songkla university

5.7.3 Study samples

5.7.3.1 Inclusion Criteria

1. Thai adult aged 18-60 years with positive dengue IgG from screening test, who not previously received dengue vaccine.
2. The subjects are able to and willing to comply with the requirements of the clinical trial program and could complete the 3-month follow-up of the study.
3. Individuals who are in good health condition at the time of entry into the trial as determined by
medical history, physical examination and clinical judgment of the investigator and meet the requirements of immunization
4. The subject can provide with informed consent and sign informed consent form

5.7.3.2 Exclusion criteria

1. Have a medical history or family history of convulsion, epilepsy, encephalopathy and psychosis.

2. Be allergic to any component of the research vaccines or used to have a history of hypersensitivity or serious reactions to vaccination.

3. Women with positive urine pregnancy test, pregnant or breast-feeding, or have a pregnancy plan within six months.

4. Have acute infectious diseases, including dengue infection

5. Have severe chronic diseases or condition in progress cannot be controlled.
For example, poor controlled DM and uncontrolled HT.

6. Have the history of urticaria 1 year before receiving the investigational vaccine.

7. Have needle sickness.

8. Have the history of immunosuppressive therapy, cytotoxic therapy or systemic corticosteroids

9. Have received blood products within 6 months before injection of investigational vaccines.

10. Not be able to follow the protocol or not be able to understand the informed consent according to the researcher's judgment, due to various medical, psychological, social or other conditions.

11. Recent administration within 1 months or planned to get any lived attenuated vaccine within the study period.

5.7.4 Subject withdrawal criteria

1. The participant chooses to withdraw from the study at any time.

2. The study is discontinued at the discretion of the investigator if continuation poses a potential risk to the participant.

3. The participant wishes to receive other vaccines (e.g., pneumococcal vaccine, zoster vaccine) within 30 days after receiving the study vaccine.

4. The participant develops anaphylaxis or any severe adverse event following the first dose of the vaccine.

5.7.5 Study termination criteria

1. The study procedures conflict with national or governmental policies.
2. New scientific evidence emerges, indicating that continuation of the study provides no meaningful benefit.
3. Intradermal vaccination results in severe local adverse events—such as abscess, granulomatous reactions, or skin necrosis—in more than 10% of study participants.

5.7.6 Sample size calculation

In this study, a total sample size of 24 participants will be used, allocated equally into two groups of 12 participants each. Based on the recommendation by Julious[13], a sample size of 12 subjects per group is considered adequate to achieve reasonable precision for preliminary estimates in a pilot study.

5.7.7 Sampling

- None

5.7.8 Study variables and their definition

Independent variables

- Technique of vaccination: subcutaneous vs. intradermal
- Sex
- Age

Dependent variables

- ELISA: Antibody level for dengue at day 0, 30, 120
- ELISpot: T cell responses against dengue antigens at day 0, 30, 120
- Adverse event following vaccine (AEFI)

5.7.9 Questionnaire/Instrument/Tool/Machine

Immunological study

Blood collection

- 15 ml of blood samples were taken before booster vaccination then 30 days after vaccination. The blood was split into 1 clotted blood tube and 2 heparinized tubes.

Sample preparation

- The sample preparation process will be done in the Biosafety Level 2. Laboratory staff will wear adequate PPEs as per BSL2 protocol.
- The samples will always be opened in BSL2 cabinet.
- The heparinized blood was spun as per PBMC separation protocol. The PBMCs were stored in liquid nitrogen for further experiments while the plasma samples kept at -80 c as well as serum from clotted blood.
- Leftover samples will be kept for 5 years for relevant immunological analysis then will be discharge as per BSL 2 protocol.

Antibody analysis

- Detection of dengue-specific human Abs by ELISA
- Mixtures of all four DENV serotypes were captured onto a MAXISORP immunoplate (NUNC) coated with mouse anti-E antibody (4G2) or anti-NS1 antibody (NS1-F3). DENV captured wells were then incubated with B cell line (BCL) culture supernatants followed

by alkaline phosphatase (AP)-conjugated anti-human IgG Abs. The reaction was visualized by the addition of PNPP substrate. The reaction was stopped with NaOH.

T cell responses

ELISpot assay

Briefly, PBMCs were added to polyvinylidene difluoride–backed plates (Millipore) precoated with a monoclonal antibody to IFN-γ (1-DIK; MABTECH). Peptides were then added at a final concentration of 10 μM and the PBMCs were cultured overnight. Cells were discarded and spots were revealed by incubation with biotinylated monoclonal antibody to IFN-γ (MABTECH) followed by streptavidin-conjugated alkaline phosphatase and substrate. The spots were counted using an AID-ELISpot Reader (Autoimmun Diagnostika). The number of specific T-cell responders was calculated after subtracting negative control values.

Peptides

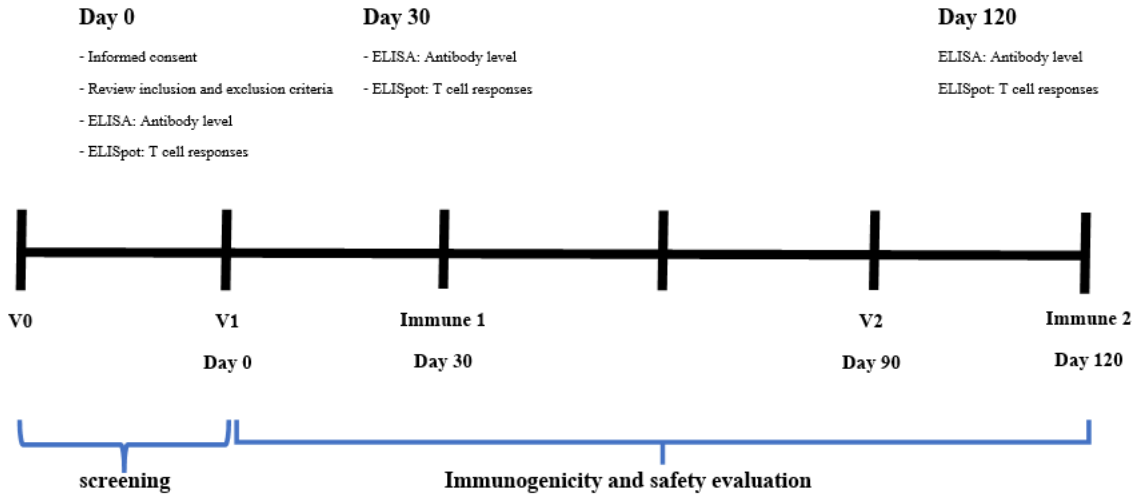
- 15-mer peptides overlapping by 5 amino acids corresponding to sequences of dengue serotype 2 strain 16681 (CprM, E, NS1, NS2, NS3, NS4, and NS5) and to the NS3 sequences of dengue serotype 1 strain Hawaii, dengue serotype 3 strain H87, and dengue serotype 4 strain H241 were synthesized to >80% purity (Sigma Aldrich). Lyophilized peptides were resuspended in dimethyl sulfoxide (DMSO; Sigma) at 80 mg/mL for peptide mixtures. The overlapping peptides were grouped together in pools corresponding to individual dengue proteins (dengue 2: CprM-26, E-97, NS1-71, NS2-70, NS3-123, NS4-70, NS5-95, dengue 1 NS3-124, dengue 3 NS3-124, and dengue 4 NS3-124). The final concentration of any single peptide was 2 μg/mL, and the final concentration of DMSO was <1% in all experiments.

5.7.10 Data collection

- Participant information will be recorded in a case record form (CRF). Personal identifiers such as name, address, date of birth, and national identification number will not be recorded. Only the hospital number will be documented for follow-up purposes, and this will be removed and replaced with a study code when transferred into the electronic database. All paper CRFs will be stored in a locked cabinet until the completion of the study.

- Immunological study data will be analyzed and stored in electronic files. The linkage between laboratory results and participant information will occur only at the final stage of the study.

Study flow



Study procedure

Study period	Screening	Treatment Vaccine dose 1	Treatment Vaccine dose 2	Follow up	
Day/week	Day 0 to -7	Day 0	Day 90 ± 3 days	Day 30 ± 3 day	Day 120 ± 3 days
Informed consent, medical history	X				
Contraceptive counselling	X				
Screen dengue IgG	X				
Review of Inclusion/ exclusion criteria		X	X		
Physical examination		X	X		
Body Weight/ Height/ Vital sign		X	X		
Concomitant medication check		X	X		

Blood collection*		X	X		X
Randomization		X			
Vaccination		X	X		
Adverse event check (also by google form+/- telephone at 7, 30 day after each vaccination)		X		X	X

Arms and Interventions:

Arm 1: subcutaneous Qdenga for 1st vaccination then intradermal Qdenga for 2nd vaccination

Arm 2: subcutaneous Qdenga for 1st vaccination then subcutaneous Qdenga for 2nd vaccination

5.7.11 Ethical Consideration

- **Informed consent process**

1. The research team will announce and publicize the study through the Line account (@psucrc) and the Clinical Research Center website to invite individuals who may be interested in participating. Participants may contact the investigators or study nurses at any time if they have questions or concerns.
2. Individuals who wish to participate may register their interest through the Line account (@psucrc) or by emailing poohsupattra@gmail.com

3. The study nurse will provide the participant information sheet and invitation documents through a method convenient for the potential participant (e.g., email or Line). Those who agree to participate will sign the consent invitation document and return it to the Clinical Research Center.
4. The study nurse will schedule study visits according to the protocol. Appointments will be arranged on weekends or public holidays to facilitate participation and avoid the need for participants to take leave from work.

- Transient vaccine viremia may occur following Qdenga vaccination. This condition has been reported in approximately 16% of individuals with prior dengue infection and 49% of those without previous dengue exposure. Symptoms typically begin during the second week after vaccination and last an average of four days. Reported symptoms

include headache, joint pain, myalgia, and rash. This event is less commonly observed after the second vaccine dose[10]

- This study does not introduce additional risks beyond those associated with the standard use of the Qdenga vaccine, which is already approved for use in Thailand. Participants will be monitored and managed according to standard clinical practice. In the event of allergic reactions or other discomfort, investigators will provide appropriate medical care.
- Blood collection may cause mild discomfort at the puncture site, minor bleeding, or bruising lasting 3–4 days. Infection at the puncture site is rare. Some individuals may experience dizziness or fainting, particularly those with needle or blood phobia. These risks will be minimized by having experienced nursing staff perform all blood draws.

5.7.12 Data management and data analysis

Data will be recorded in case record forms and subsequently entered into an electronic database using Microsoft Excel. Statistical analyses will be performed using the R software environment.

Data analysis

(1) Record and analyze data: using the R program version 3.5.1

(2) Analysis data:

- Continuous variables using Mean ± SD or Median (IQR)
- Discrete variables using percentage
- Compare qualitative variables data using Pearson's Chi-squared test or Fisher's exact test
- Compare quantitative variables data using Student's t-test or Wilcoxon rank-sum test
- A probability value (P) <0.05 was considered significant

5.7.13 Study duration

1 year, from 1 April 2025 to 30 September 2025.

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