RINGKASAN HASIL EVALUASI
PERMOHONAN PERSETUJUAN PELAKSANAAN UJI KLINIK
VAKSIN BCG
PRODUKSI PT. BIOFARMA

Informasi Umum

Kebutuhan vaksin BCG untuk program imunisasi di Indonesia telah dipenuhi oleh PT. Bio Farma dalam bentuk ampul. Untuk mengantisipasi peningkatan kebutuhan dan perbaikan kemasan vaksin, maka PT. Bio Farma memproduksi vaksin BCG dalam kemasan vial.

Informasi Uji Klinik

1.	Judul Protokol	:	*Safety and Tuberculin Conversion Following BCG vaccine vial (Bio Farma) compared to Registered BCG vaccine (Bio Farma) in Indonesian Infants* (versi 1.a, September 2021)
2.	Produk Uji	:	BCG Vaccine Vial diberikan 1 kali secara intradermal Produsen PT. Bio Farma
3.	Produk Pembanding	:	BCG Vaccine Ampul 1 kali secara intradermal Produsen PT. Bio Farma
4.	Center / Peneliti	:	Departemen Ilmu Kesehatan Anak RSUD Dr. Soetomo Surabaya / Dr. Dominicus Husada, dr., SpA(K).
5.	Sponsor / ORK	:	PT. Bio Farma
6.	Persetujuan Etik	:	No. 0285/KEPK/X/2021 tanggal 21 Oktober 2021 dari Komite Etik Penelitian Kesehatan RSUD Dr. Soetomo Surabaya.
7.	Desain Uji Klinik	:	*Randomized, observer-blind, prospective intervention study*
8.	Jumlah Subjek	:	*220 subjects*
9.	Tujuan Uji Klinik	:	*Primary Objective* *To evaluate the safety of BCG Vaccine Vial (Bio Farma)* *Secondary Objective* - *To assess the local and systemic reactions within 30 minutes, 24 hours, 48 hours, 72 hours, 7 days and 30 days after vaccination.* - *To assess local reactions at 60 days and 90 days after vaccination in each group.* - *To assess serious adverse events within 30 days after vaccination in each group.* - *To assess the tuberculin conversion in each group.*
10.	Kriteria Eligibilitas	:	Kriteria Inklusi / *Inclusion criteria* 1. *Healthy infant aged 0-1 month.* 2. *Infants born after 37-42 weeks of pregnancy.* 3. *Infant weighing 2500 gram or more at birth.* 4. *Father, mother or legally acceptable representative properly informed about the study and having signed the informed consent form.* 5. *Parents will commit themselves to comply with the instructions of the investigator and with the schedule of the trial.* Kriteria Eksklusi / *Exclusion criteria* 1. *Child concomitantly enrolled or scheduled to be enrolled in another trial.*

2. *Evolving moderate or severe illness, especially infectious diseases or fever (axillary temperature ε 37.5℃).*
3. *Suspected of allergy to any component of the vaccines.*
4. *Newborn suspected of congenital or acquired immunodeficiency.*
5. *Received or plans to receive any treatment likely to alter the immune response intravenous (immunoglobulins, blood-derived products or long term corticotherapy (> 2 weeks)).*
6. *Received other vaccination with the exception of OPV and Hepatitis B vaccine.*
7. *Any abnormality or chronic disease which according to the investigator might interfere with the assessment of the trial objectives.*
8. *Any skin disease such eczema generalisata other skin infection which makes difficult the assessment of the local reactios.*
9. *Mothers with HbsAg and HIV positive (by rapid test)*
10. *Parents planning to move from the study area before the end of study period.*

11. Luaran Uji Klinik*/Endpoint* **:** **Luaran Primer /** *Primary Endpoints*:
Number and percentage of subjects experiencing local reactions and/or systemic events within 30 minutes after vaccinations.

Luaran Sekunder **/** *Secondary endpoints*
- *Local reaction and systemic events occurring within 24 hours, 48 hours and 72 hours after vaccination.*
- *Local reaction and systemic events occurring within 7 days after vaccination.*
- *Local reaction and systemic events occurring within 30 days after vaccination.*
- *Local reaction and systemic events occurring at 60 days and 90 days after vaccination.*
- *Any serious adverse event occurring from inclusion until 30 days after vaccination.*
- *Percentage of subjects having tuberculin conversion.*
- *Comparison of adverse events between investigational product (IP) and control.*

Ringkasan Hasil Evaluasi

Badan POM telah melakukan evaluasi protokol yang diajukan yang didukung oleh tim ahli melalui rapat pada tanggal 17 september 2021 dengan hasil sebagai berikut:

1. Uji klinik untuk membandingkan Vaksin BCG vial dengan Vaksin BCG ampul yang telah teregistrasi bertujuan untuk menilai kesetaraan imunogenisitas dan keamanan vaksin.
2. Adanya perubahan kemasan vaksin BCG yang semula ampul menjadi vial menyebabkan beberapa perubahan antara lain perubahan jumlah bakteri yang semula 1,5 – 6 juta cfu menjadi 2 – 8 juta cfu (optimasi proses formulasi).
3. Desain uji klinik yang diajukan dapat diterima.
4. Vaksin memenuhi persyaratan mutu.

Keputusan

Pelaksanaan uji klinik dengan protokol di atas disetujui melalui penerbitan Persetujuan Pelaksanaan Uji Klinik (PPUK) No. RG.01.06.1.3.11.21.59 tanggal 22 November 2021