Effect of Vitamin D as Adjuvant Therapy in Preterm Infants With Neonatal Sepsis

Informed Consent Form

Version 1
1st June 2025

NCT Number: NCT ID not yet assigned
Unique Protocol Id: DP. 04.03/D.XIV.6.5/337/2025

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HEALTH RESEARCH ETHICS COMMITTEE
Jl. Pasteur No. 38 Bandung 40161

Form 2

INFORMATION

"Effect of Vitamin D as Adjuvant Therapy in Preterm Infants with Neonatal Sepsis"

Research Access:

Research Team consists of:

NO.	RESEARCH TEAM	PHONE
1.	Michelle Angelica Wijaya	081313996911
2.	Dr. Reni Ghrahani, dr., Sp.A(K)., M.Kes	08122111482
3.	Dr. Fiva Aprilia Kadi, dr., Sp.A(K)., M.Kes	081120050111

Background :

Neonatal sepsis is a disease caused by the presence of bacteria in the blood occurring in the first month of life. The immune system in infants, especially premature babies, is not fully developed, making them more susceptible to infection. Neonatal sepsis is treated by administering antibiotics via infusion. However, recent studies are still exploring various other therapies that can aid the healing process of neonatal sepsis.

Some recent research has found that vitamin D is related to sepsis. Vitamin D plays a role in the immune system and can help accelerate the reduction of inflammation markers and infection in the body. Vitamin D also has a low risk of toxicity/overdose, minimal side effects, and is affordable. Research on the effect of vitamin D as an adjuvant therapy in neonatal sepsis is still very limited globally, and in Indonesia, there have been no similar studies to date.

Objective:

To evaluate the effect of vitamin D administration as an adjuvant therapy in neonatal sepsis by measuring differences in sepsis scores and CRP levels.

Why your child is selected:

Your child meets the criteria, which is being a premature infant diagnosed with neonatal sepsis and without any major congenital abnormalities.

Benefits:

Your child's vitamin D levels will be examined and, if possible (if able to take orally), will be given additional vitamin D therapy. It is hoped that by understanding the effect of vitamin D as an adjunct therapy for neonatal sepsis, it can serve as a consideration for vitamin D administration in such cases.

Potential Discomfort and Risks:

Pain during blood sampling: Pain management for infants will be provided, such as pacifiers with sugar/breastmilk. Risk of infection and bruising/hematoma: Sterile equipment will be used, and antiseptic techniques applied before

blood collection. Bruises will be treated with a cold compress using gauze and 0.9% NaCl infusion fluid.

Possibility of Unknown Risks:

Vitamin D overdose/toxicity, such as excess calcium levels in the blood.

Procedure:

1. Parents/guardians of participants diagnosed with neonatal sepsis and who meet the research criteria will be given a detailed explanation of the research, and after agreeing, will be asked to sign an informed consent form.
2. Blood samples of 4 mL will be taken from a vein on Day 0 and Day 7, along with other evaluation blood tests.
3. Patients selected for the treatment group will receive additional vitamin D3 (either 1x400 IU or 1x800 IU daily) for 7 days, with laboratory evaluation done on Day 0 and Day 7.
4. Data will be collected and statistically analyzed.

Complications and Compensation:

Medical treatment will be provided if there's any complication related to this study

Can the subjects be withdrawn or withdraw themselves from the study?:

Yes

Data Confidentiality:

Your child's data will be kept confidential

Bandung, 1st June 2025
Principal Investigator

Michelle Angelica Wijaya

Jl. Pasteur No. 38 Bandung	**INFORMED CONSENT FORM TO PARTICIPATE IN RESEARCH**

INFORMATION

Principal Investigator: dr. Michelle Angelica Wijaya

Name of the person providing information:

Research participant:

Witness:

NO	INFORMATION	CONTENT OF INFORMATION
1	Explanation about the research, duration of the research subject's participation, and procedures that must be followed by the subject	The study will be conducted for 7 days from the time the patient is diagnosed with neonatal sepsis. Blood samples will be taken twice, on day 0 and day 7, with a volume of 4 mL each time. For patients who are not fasting, those in the treatment group will be given additional vitamin D3 at a dose of 1x400 IU (0.5 mL) or 1x800 IU (1 mL) daily for 7 days, in addition to antibiotic administration.
2	Expected benefits	Subjects participating in the study can know their 25(OH)D levels, and those in the treatment group will receive vitamin D3 supplementation as an additional therapy.
3	Potential discomforts and risks that may arise	Pain during blood collection
4	Alternative treatments and procedures that also provide benefits	None
5	Maintain the confidentiality of research data	The confidentiality of the subject's data is guaranteed.
6	Provision of compensation or medical treatment if complications occur	Yes, medical treatment will be provided
7	Participation is voluntary	Participation in this research is voluntary.
8	Refusal to participate or withdrawal from the study will not affect your access to hospital services, nor will it compromise the care you receive.	The parent/guardian of the subject has the right to refuse participation and will not face any penalties, nor will it compromise the care or access to hospital services.
9	If you have any questions or need more information, please contact	Michelle (Phone: 081313996911)
10	Others	None

I hereby declare that I (principal investigator) have explained the above matters correctly and clearly, and have provided the opportunity to ask questions and/or discuss.	Principal Investigator (Michelle Angelica)

I hereby declare that I (the patient's guardian) have received the information from the person in charge of the research as stated above and have understood it.	Patient's guardian*) (_____) Signature and name Witness (_____) Signature and name

STATEMENT OF CONSENT

The person(s) signing below:

Medical record : .....
Name : .....
Date of Birth :.....**Male/Female*)**
Address : .....
.....
Occupation : .....
Identity number : .....

Hereby declare that:
After receiving a full explanation, I am aware of, understand, and comprehend the purpose, benefits, and potential risks that may arise in the research, and that I may withdraw and cancel my participation in the study titled:

"Effect of Vitamin D as Adjuvant Therapy in Preterm Infants with Neonatal Sepsis"

herefore, I declare:
Agree / Disagree*) …… to let my child participate in this research.

This statement is made truthfully and without any coercion,

Bandung, ... 2025 Time.....

The undersigned.	**Principal Investigator**	**Witness**
(……)	(dr. Michelle Angelica Wijaya)	(……)
Signature and name	Signature and name	Signature and name

RM.IC.06/15

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Form 3

STATEMENT OF CONSENT TO PARTICIPATE IN RESEARCH (INFORMED CONSENT)

The undersigned:

Name:

Age:

Address:

Occupation:

ID Number:

Who is the parent/guardian of:

Name :
Medical Record :
Age :
Address :

Hereby declare that:

After receiving a full explanation, I am fully aware of, understand, and comprehend the purpose, benefits, and possible risks that may arise in this research, and that I may withdraw and cancel my participation at any time in the study titled:

"Effect of Vitamin D as Adjuvant Therapy in Preterm Infants with Neonatal Sepsis"

Therefore, I hereby declare:
Agree and give permission / Do not agree and do not give permission* for my child to participate in this research.

This statement is made truthfully and without coercion.

Witnesses :

Bandung, 2025

Parent/guardian of the research participant

(……)

(.....)

(……..)

(*) The participant can select either "Agree and give permission" or "Do not agree and do not give permission."