

**Title:**

Effects of Nigella Sativa on T Cells, Cytokine Profile, and SLEDAI Score in Pediatric SLE Patients

**NCT number:**

NCT ID not yet assigned

**Document date:**

31 July 2024

## **Parent/Guardian Consent Form and Child Assent Form**

### **Title of the Study:**

The effects of Nigella sativa supplementation on T lymphocytes and inflammatory cytokines profile in pediatric systemic lupus erythematosus: a randomized controlled trial

### **Principal Investigator:**

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### **Purpose of the Study:**

Your child is invited to participate in a research study. The purpose of this study is to investigate the immune-modulatory effect of Nigella sativa oil (NSO) supplementation in pediatric patients with SLE.

### **Procedures:**

If you agree that your child participate in this study, your child will be asked to get supplement in a capsule in daily doses for 8 weeks. Before and after treatment, your child will be asked to undergo a blood draw. Approximately 5 ml of blood will be collected from a vein. This procedure will be performed by a trained healthcare professional and will take approximately 10 minutes. The blood samples will be used to analyze cytokines including of IFN- $\gamma$ , TNF- $\alpha$ , IL-2, IL-4, IL-6, IL-17 and T cell lymphocyte profile including Th1, Th2, Th17, Treg. The study will take approximately 8 weeks of duration.

### **Risks and Discomforts:**

There are no known significant risks associated with this study. However, any potential risks, even if minimal, such as nausea or abdominal pain, and painful sensation during blood collection. If you feel uncomfortable at any point, you may withdraw from the study without any consequences.

### **Benefits:**

The possible benefits of participating in this study include receiving information about cytokine and T lymphocyte profile in subject, get close monitoring, and contributing to scientific knowledge,

### **Confidentiality:**

Your participation in this study is confidential. The information you provide will be coded to ensure anonymity, and only the research team will have access to the data. The results of this

study may be published or presented at scientific conferences, but your identity will not be disclosed.

**Voluntary Participation:**

Your participation in this study is entirely voluntary. You and your child may decline to participate or withdraw from the study at any time without any consequences.

**Contact Information:**

If you have any questions or concerns about this study or have questions about your rights as a research participant, please feel free to contact Wisnu Barlianto at +62 812-3319-895.

**Parent/Guardian Consent:**

By signing below, you indicate that you have read and understood the information above and agree to your child's participation in this study. You will receive a copy of this form for your records.

Parent/Guardian's Name: \_\_\_\_\_

Parent/Guardian's Signature: \_\_\_\_\_

Date: \_\_\_\_\_

**Child Assent:**

We also want to ask your child if they are willing to take part in this study. Please explain this information to your child and encourage them to ask any questions they may have.

Child's Name: \_\_\_\_\_

Child's Signature (if appropriate): \_\_\_\_\_

Date: \_\_\_\_\_