

Sleep and Adolescent Vaccine Immunogenicity Pilot/Observational Study

Status: RECRUITING

Eligibility Criteria

Sex: ALL

Age: 11 years to 12 years old

Healthy Volunteers: This study is also accepting healthy volunteers

Inclusion Criteria:

- Healthy 11-12 years olds who have neither had initial meningococcal vaccination nor known exposure to meningococcal illness.

Exclusion Criteria:

- Condition or treatment resulting in immunosuppression
- Prior severe vaccine reaction
- Symptoms of clinical insomnia or organic sleep disorder
- Known neurologic condition or intellectual/developmental disability
- Use of a medication that impacts sleep
- Average nightly sleep of 8-8.99 hours (between the two groups)
- Daily intake of >1 coffee or "energy drink" or >2 caffeinated sodas.

Conditions & Interventions

Conditions:

Vaccination

Keywords:

Sleep

More Information

Description:

The main reason for this research study is to understand whether the sleep habits of 11-12 years-olds impact their response to a vaccine. The vaccine is called MCV4. It protects against meningococcal illness, which is rare but can be severe. The American Academy of Pediatrics recommends that the vaccine be given at age 11 or 12. The vaccine has been approved for youth in this age range for over 20 years and is one of the vaccines that primary care doctors typically give around this age. However, nobody has studied how sleep affects children's response to it. This could be important because research on adults suggests that sleep affects the immune system. We want to look at that issue in a younger age range. Participating families will be asked to have their child keep their regular sleep schedule during the 5-week study, without much variation. During that time, they will wear a special wristwatch at night to track their sleep. Each day they will fill out a short online form. They and a parent/guardian will come to Cincinnati Children's twice. Each visit will last 1 - 1 ½ hours. The first visit will happen at the end of the 1st week. The second is at the end of the 5th week. During visits, they will fill out forms and we will get data from the wristwatch. During the first visit, the participating child would get the vaccine. During the second, they will have a blood test.

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Principal Investigator:

Principal Investigator ID:

Phase:

IRB Number:

System ID: NCT07636525

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