

Official Title: Effectiveness of Nasal Suction in Infants with Bronchiolitis Using a NoseFrida vs Bulb Syringe

NCT Number: NCT04599101

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### **Information Sheet with Identifiers**

**Study Title:** Effectiveness of nasal suction in infants with bronchiolitis using a NoseFrida vs. bulb syringe: a prospective observational study

**Principal Investigator:** Margaret Menoch, MD

**Address:** 3601 W. 13 Mile Rd, Royal Oak, MI, 48073

**Hospital:**

William Beaumont Hospital (Royal Oak)

**Purpose:**

You are being asked to be in a research study to evaluate the difference in effectiveness of nasal suction between two different suction devices (NoseFrida and bulb syringe) in infants that have bronchiolitis. This study is being conducted at William Beaumont Hospital.

**Study Procedures:**

If you decide to take part in the study, we will be reviewing your child's medical record for information regarding their history of respiratory distress. You will be given two devices to take home, the NoseFrida and bulb syringe. Depending on the week we will ask you to use one of the devices first and then to alternate between the two. These devices should be used to clear nasal secretions as needed throughout the five days following discharge from the Emergency Center. You will also monitor a few aspects of how well your baby is doing, including:

- how well your baby is breathing,
- how well your baby is eating/drinking,
- how well your baby is sleeping,
- and if you return to the emergency center in the 5 days following discharge from the emergency center.

At 5 days after discharge from the Emergency Center, we will email you a survey via REDCap which will ask questions about how your baby has been doing over the past week (this may take 5-10 minutes). This will then complete your involvement in the study. The suction device will be yours to keep.

**Participation:**

By verbally consenting in the Emergency Center, and by completing the REDCap survey after discharge, you are agreeing to participate in this study.

**Benefits:**

As a participant in this research study, there may be no direct benefits for you; however, information from this study may benefit other people now or in the near future.

**Risks:**

Beaumont is committed to upholding strict confidentiality in research and all business practices, however there could be a rare risk of loss of confidentiality. We are very concerned about your privacy and will make every effort to maintain the security of your records.

**Costs:**

There will be no costs to you for participating in this research study.

**Compensation:**

You will be offered a \$10 gift card for completion of the survey.

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THIS INFORMATION SHEET IS FOR THE PARTICIPANT TO KEEP

IRB NUMBER: 2020-325  
IRB APPROVAL DATE: 09/15/2023  
IRB EXPIRATION DATE: 09/14/2024

**Confidentiality:** All information collected from you and your health record will be kept securely in a method approved by Beaumont.

**Voluntary Participation/Withdrawal:**

Taking part in this study is voluntary. You may choose not to take part in this study, or if you decide to take part, you can change your mind later and withdraw from the study. Your decision will not change any present or future relationships with William Beaumont Hospital or its affiliates. If you are employed by William Beaumont Hospital or its affiliates, as an employee your participation is completely voluntary and will not impact your job in a positive or negative manner.

**Questions:**

If you have any questions about this study now or in the future, you may contact Margaret Menoch, MD or one of his research team at the following email: [Bronchiolitis@Beaumont.org](mailto:Bronchiolitis@Beaumont.org). If you have questions or concerns about your rights as a research participant, please contact the Institutional Review Board at 248-551-0662. The Institutional Review Board is charged with the oversight of all human participant research conducted at Beaumont facilities.