

## Asthma: Effects of Genotype on Response to Therapy

DO NOT SKIP ANY STEPS OF THE PROTOCOL OR LEAVE ANYTHING BLANK ON DATA OR LOG SHEET. IF SOMETHING IS NOT RECORDED, STATE WHY IT WAS NOT INCLUDED IN THE LOG SHEET. BE AS DETAILED AS POSSIBLE.

Version 6/11/2008

### Inclusion Criteria

- Age 18 – 54 yrs old
- Ability to give informed consent
- NOT pregnant, no jail patients
- History of asthma
- Pulse Oximetry on arrival to ED  $\geq$  92%
- Signs and symptoms consistent with acute asthma exacerbation including but not limited to dyspnea, hypoxia, wheezing, etc
- NO other lung disease such as CHF, TB or pneumonia
  - If patient states that they have asthma AND emphysema or COPD they CAN be enrolled
- NO allergy to Albuterol
- NO presence of fever  $>$  100°F
- Patients who have received any treatments prior to arrival CAN be enrolled in the study as of 05/06/2008.

### Study Materials (in research locker)

- Asthma Informed Consents (English and Spanish)
- Asthma Data Collection Sheets
- Asthma Patient Log Sheet
- Green topped, sodium heparin vacutainers for blood specimens labeled with appropriate study code
- Cooler and ice packs for specimens

### Study Steps

1. **START OF SHIFT:** Introduce yourself to attending physician, residents, nurses who are caring for the asthma patients in the asthma booth.
  - When an asthma patient is brought to booth, hook up pulse oximetry sensor and obtain peak flow using spirometer (for directions on spirometer use, refer to complete Asthma Protocol version date 4.14.08, pg. 2 in Research Locker)
2. **INTRODUCE** yourself to the patient and determine if he/she fits inclusion criteria for study. If yes, introduce and explain the study, that it is voluntary, and ask for consent.
3. **PATIENT CONSENTS TO STUDY**
  - Inform nurse and physician in area that the patient has consented to be in the study and will not be receiving Atrovent in their treatments. If the physician believes that the patient needs Atrovent, the patient cannot be enrolled in the study.
  - To expedite time to first treatment, continue on to steps 4 and 5 before getting signatures on the informed consent
4. **BASELINE MEASUREMENTS** (before patient receives any treatments)
  - Asthma Data Sheet p.2
    - Record Blood Pressure (SBP, DBP), Pulse, Oxygen saturation (pulse ox), Respiratory rate.
      - For BASELINE measurements, these can be found in patient's chart.
      - For directions how to get these measurements following additional treatments, refer to complete Asthma Protocol version date 12/21/07 in Research Locker
    - Obtain and record Forced Expiratory Volume (FEV1) using spirometer
    - Obtain and record Peak Expiratory Flow (PEF) using spirometer
      - For information on how to obtain FEV1 and PEF, refer to complete Asthma Protocol version date 4.14.08 pg.2 in Research Locker
    - Obtain and record Borg Scale Number using Modified Borg Scale sheet in clipboard. "Pick a number that best describes your shortness of breath"
    - Obtain and record Breathlessness Line Scale (Data Sheet Page 3). Ask patient to mark an "x" on the 10 cm line at the location that best describes how they feel, with right side of line being the worst breathlessness they have ever had and left side of line being NO breathlessness.
5. **FIRST TREATMENT**
  - 5mg Albuterol administered via hand-held nebulizer
  - Only nurse or doctor can place the medication in the nebulizer

QUESTIONS? PLEASE REFER TO COMPLETE ASTHMA PROTOCOL VERSION DATE 4.14.08 OR REFER TO CONTACT INFORMATION IN RESEARCH LOCKER

## Asthma: Effects of Genotype on Response to Therapy

DO NOT SKIP ANY STEPS OF THE PROTOCOL OR LEAVE ANYTHING BLANK ON DATA OR LOG SHEET. IF SOMETHING IS NOT RECORDED, STATE WHY IT WAS NOT INCLUDED IN THE LOG SHEET. BE AS DETAILED AS POSSIBLE.

Version 6/11/2008

- A**
- S**
- T**
- H**
6. **CONSENT PATIENT (DURING FIRST TREATMENT)**
    - 3 signatures from patient required on the informed consent, one signature from research student, one from witness
    - Make two additional copies of the consent. The original form goes in the patient's chart, one copy is given directly to the patient, one copy is placed in the research locker "completed forms" folder
  7. **COMPLETE ASTHMA DATA SHEET PAGE 1 (In between treatments)**
    - **KEY**
      - DOS=Date of service
      - Generation: 1<sup>st</sup> = Not born in US, 2<sup>nd</sup> = Patient's parent not born in US, 3<sup>rd</sup>=Patient's grandparents not born in US
      - Number of times to ED and Number of times Hospitalized in the last month and year = number of times SPECIFICALLY for asthma
      - Medication History=All medications and dosages the patient is CURRENTLY taking
      - Medications Prior to Arrival = what the patient has taken the day of their visit to ED
      - Complications this visit (page 2). If no complications, write "none" on "Other" line
      - Admit/Dispo Time (page 2)
      - Check off if patient received chest x-ray (CXR), Magnesium (Mg), or IV fluids while in asthma booth (IV) (page 2)
  8. **BETWEEN EACH TREATMENT**
    - Record Time of treatment, Blood Pressure (SBP and DBP), pulse, oxygen saturation, respiratory rate, PEF, FEV1, and Borg scale (Asthma Data Sheet pg 2)
    - Record Breathlessness Line Scale value. Cover up previous recordings the patient made when giving it each time.
  9. **BLOOD SAMPLE**
    - The blood sample can be drawn at any time during the patient's stay in the ED. Two 10ml green top heparinized vacutainer must be filled three quarters of the way full in order to obtain a suitable plasma sample. Be sure to label each vacutainers with "Asthma" and the study number. Once blood has been collected into the green-topped tubes, invert at least 5x slowly to completely mix the anticoagulant. Avoid prolonged exposure to light; place the two tubes immediately into a bag and store the samples in the cooler. The blood may freeze and DNA may be lost if samples are in direct contact with the ice pack/bag of ice. Place bagged samples in small box provided in cooler.
    - Place cooler back in research locker. Research assistants will get it the next morning for processing.
  10. **PHOTOCOPY YELLOW**
    - Get a copy of the yellow (patient chart) before the patient is discharged but after they've completed their treatments
    - Put with the data sheet into the red completed data sheet folder in the locker

### **M** Documentation

- The patient's study number, name, date of and MRUN number must be recorded on the Asthma MRUN log
- A copy of the patient's entire chart must be obtained after they have been released/admitted. If they were not released/admitted during your shift, indicate so in the log
- If the doctor determines that the patient needs to receive Atrovent because Albuterol alone is not working, indicate so on the data sheet. The patient can still be in the study, but we can only use the data we collected before they received the Atrovent
- Log all asthma patients on the Asthma Misses and Deviations Log sheet. If the patient is enrolled, indicate the treatment that received. If the patient could not be enrolled in the study, indicate the reason he/she had to be excluded or why he/she did not want to participate
- Document any deviations from the protocol!
- Document everything!

**A**

QUESTIONS? PLEASE REFER TO COMPLETE ASTHMA PROTOCOL VERSION DATE 4.14.08 OR REFER TO CONTACT INFORMATION IN RESEARCH LOCKER