

PROJECT BRIEF

AZMATICS: AZithroMycin/Asthma Trial In Community Settings

Study Principal Investigator: David Hahn, MD, MS

Background

The etiology of asthma is currently unknown. It has been shown, however, that *Chlamydia pneumoniae* infection is associated with asthma. Preliminary open-label and randomized trials suggest a positive effect of antibiotics on asthma symptoms. A pilot randomized controlled trial (RCT) indicated positive symptom improvement 3 months after completing 6 weeks of azithromycin treatment, but no effect on *C. pneumoniae* antibody levels was found. This current study is a RCT designed to investigate whether a 12-week course of azithromycin will improve asthma clinical status up to one year after treatment.

Study Question

Does azithromycin improve asthma symptoms, asthma medication use, exacerbations and quality of life among adult asthma patients typically encountered in clinical practice, and does the improvement persist after treatment is completed?

Intervention

The study will provide tablets of azithromycin or matching placebo to participants for 3 months: one tablet daily for 3 days, then one tablet each week for 11 weeks. Each tablet contains 600 mg azithromycin or matching placebo.

Measurement

Research staff collect demographic and asthma-related information during the patient's baseline visit. Follow-up information is collected in Internet

surveys on a predetermined schedule. Such surveys may be completed directly by the subject or conducted over the telephone with the subject by trained study personnel. Information collected includes asthma symptoms, medication use, control, exacerbations, quality of life and adverse events ongoing for 12 months after randomization.

Eligibility

- Age 18 or older
- English literate with telephone OR email and Internet access
- Physician-diagnosed asthma that is persistently symptomatic, or in exacerbation; plus objective evidence for reversible airway obstruction by spirometry or by peak flow within 2 years of enrollment

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Population

At least 6 adult patients from clinics at Aurora Sinai Medical Center and St. Luke's Medical Center.

Timeline

Participants take study medication for a period of 12 weeks. Survey follow-up for subjects continues for one year (online or by telephone). Study recruitment is slated to end in August 2009. Data collection will end one year after the last patient is enrolled in the study.

Funding Sources

- American Academy of Family Physicians Foundation
- Wisconsin Academy of Family Physicians
- Wisconsin Network for Health Research (WiNHR)
- Pfizer (in-kind supply of study drug)

Supporting Network Information

The Wisconsin Research and Education Network (WREN) and the Wisconsin Network for Health Research (WiNHR) provide support for this research. These organizations are integral components of the University of Wisconsin School of Medicine and Public Health Institute for Clinical and Translational Research.

Local Principal Investigators

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Local Participating Clinics

- Aurora Sinai Family Care Center
- Aurora UW Medical Group Family Practice Center located at St. Luke's
- Aurora Sinai Internal Medicine Clinic

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Or visit the WREN website at:
<http://www.wren.wisc.edu/>

For more information on WiNHR, visit:
<http://www.cuph.org/winhr>

The Center for Urban Population Health is a partnership among the University of Wisconsin School of Medicine and Public Health, the University of Wisconsin-Milwaukee, and Aurora Health Care, Inc. Our mission is advancing population health research and education to improve the health of urban communities.