

Jennifer F. Friedman, MD, at RIH confirms anti-parasitic drug safe for pregnant women after first trimester

Finding could spur improved access to treatment to millions of women in developing countries

PROVIDENCE – A study by Rhode Island Hospital researchers confirmed that a drug used to treat a disease afflicting millions of people in developing countries is safe to give pregnant women following their first trimester. The finding could prove critical to the care of pregnant women and lactating women with schistosomiasis, a disease caused by a parasitic worm, who were denied the drug out of concern for their health and the health of their fetuses.

Authored by **JENNIFER F. FRIEDMAN, MD, PHD, MPH**, director of clinical studies for the Center for International Health Research at Rhode Island Hospital, the study found that praziquantel does not lead to adverse events for the pregnant woman or her newborn. The study was published today in *The Lancet Infectious Diseases*.

“Millions of women, many of whom are in a multi-year, cyclical pattern of pregnancy and breast-feeding, are denied praziquantel,” said Dr. Friedman. “The accumulation of evidence shows that commencement of this treatment after the first trimester does not adversely affect the mother or fetus. We wanted to conduct this study to demonstrate that this drug is safe after the first trimester, and we remain hopeful that public health policies will change. Deferring treatment only exacerbates the morbidity of the patients.”

Nearly 40 million women of reproductive age are infected with schistosomes. They are a significant cause of disease in developing countries. Despite World Health Organization recommendations to offer pregnant women treatment with praziquantel, many nations continue to withhold treatment, awaiting safety and efficacy data from controlled drug trials such as this one.

Schistosomiasis is transmitted during contact with freshwater containing snails that have been infected due to poor sanitation practices. It is known to cause damage to the kidneys, liver, bladder and other organs. After malaria, schistosomiasis is the most common parasitic disease, affecting 200 million people throughout the world and kills approximately 280,000 people annually.

No previous study has examined whether praziquantel treatment at 12–16 weeks gestation improves pregnancy outcomes or whether the use of a higher dose of praziquantel recommended to treat Asian schistosomiasis can be safely administered without adverse newborn or maternal outcomes. This research study, conducted in the Philippines, found that treatment did not positively impact birth weight, however, the iron status of the mothers and newborns improved in the treated group. ❖

RIH, Hasbro EDs to participate in research trial for seizure medicines

PROVIDENCE – The emergency departments of Rhode Island Hospital and its pediatric division, Hasbro Children’s Hospital, are participating in a research study to compare three seizure medications administered during emergencies. The seizure study, known as Established Status Epilepticus Treatment Trial (ESETT), is sponsored by the National Institutes of Health.

Fosphenytoin, levetiracetam, and valproic acid are used to treat seizures in the U.S. emergency departments. However, it is not known which drug is the best drug to stop persistent seizures, a condition called status epilepticus. A clinical trial to study these drugs will be initiated at Rhode Island and Hasbro Children’s hospitals. Persons affected by seizures can decline enrollment in the ESETT study by contacting the study leadership and requesting an “opt out” medical bracelet.

Eligible patients who present to the emergency department with a seizure that does not respond to standard first line therapy (a drug called a benzodiazepine) will be enrolled in the ESETT study. One of the three study medicines will be provided. The ESETT study will assess which seizure medication is the best at stopping the seizure. As soon as possible after enrollment, the hospitals will attempt to obtain consent from the patients or their legal representatives for continued participation in the study. Patients may withdraw from the study at any time.

Hospitals are required to inform the community when the U.S. Food and Drug Administration authorizes a study to be conducted under exception from informed consent. This study meets all four criteria for such exception because: 1) the patient’s life at risk; 2) the treatments currently used are unproven; 3) the best treatment is not known; and 4) it is not possible to get permission from the patient because of his or her medical condition or from the person’s legally authorized representative because the medical problem must be treated very quickly. ❖

ICDs approved for use in MRI scans now being implanted at CNE hospitals

PAWTUCKET – Care New England Cardiovascular Care is now offering patients an implantable cardioverter defibrillator (ICD) system approved by the FDA for use with magnetic resonance imaging (MRI) scans. The first implant of this type of device in Rhode Island was performed recently at Memorial Hospital in Pawtucket.

“Patients with ICDs are often older adults with other serious medical conditions that require an MRI for diagnosis,” said **BRUCE KOPLAN, MD, MPH**, director of Cardiac Arrhythmia Services for Care New England and a member of the Brigham and Women’s Cardiovascular Associates at Care New England, who performed the procedure. “We’re grateful to have this new technology that helps treat cardiac arrest and still enables patients to access MRIs.” ❖