



Prairie

EDUCATION & RESEARCH COOPERATIVE

326 North 7th Street, Suite 101, Springfield, IL 62701 • (217) 544-6464 X 66044 • Fax: (217) 522-1206

RESPECT PFO

<u>Trial Sponsor:</u>	AGA Medical Corporation
<u>Principal Investigator:</u>	Joni Clark, MD / Tony DeMartini, MD
<u>Trial Name:</u>	Randomized Evaluation of Recurrent Stroke Comparing PFO Closure to Established Current Standard of Care Treatment
<u>Purpose:</u>	The purpose of this study is to investigate whether percutaneous Patent Foramen Ovale (PFO) closure, using the AMPLATZER PFO Occluder, is superior to current standard of care medical treatment in the prevention of recurrent embolic stroke.
<u>Phase:</u>	Phase II
<u>Study Type:</u>	Interventional
<u>Study Design:</u>	Prevention, Randomized, Open Label, Uncontrolled, Single Group Assignment, Safety/Efficacy Study
<u>Expected Enrollment:</u>	500
<u>Study Start:</u>	August 2003

Eligibility

Ages Eligible for Study: 18 – 60 Years

Genders Eligible for Study: Both

Inclusion Criteria:

- Subjects who have had a cryptogenic stroke within the last 270 days
- Subjects who have been diagnosed with a Patent Foramen Ovale (PFO)
- Subjects willing to participate in follow-up visits



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Exclusion Criteria:

- Subjects with intracardiac thrombus or tumor
- Subjects who have an acute or recent (within 6 months) myocardial infarction or unstable angina
- Subjects with left ventricular aneurysm or akinesis
- Subjects with atrial fibrillation/ atrial flutter (chronic or intermittent)
- Subjects with another source of right to left shunt identified at baseline, including an atrial septal defect and/or fenestrated septum
- Subjects with contraindication to aspirin or Clopidogrel therapy
- Pregnant or desire to become pregnant within the next year