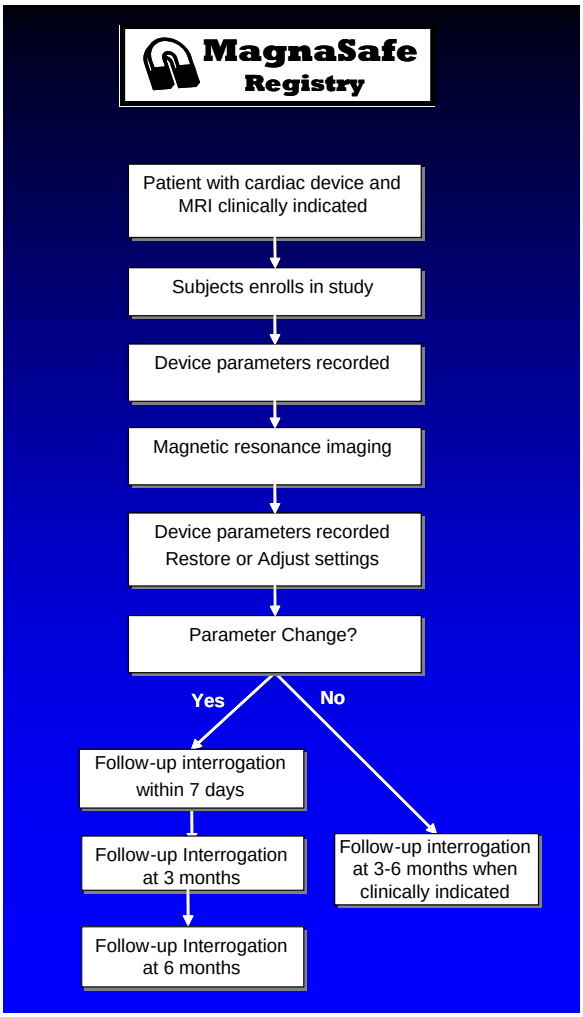
MagnaSafe
Multicenter Registry

Determining the Safety of MRI for Patients with Pacemakers and Implantable Cardioverter-Defibrillators

The MagnaSafe Registry is a prospective multi-center study designed to determine the safety of non-thoracic 1.5T MRI scanning for patients with implanted cardiac devices. Patients with pacemakers or ICDs scheduled for a clinically-indicated MRI will be invited to enroll in the study. In this protocol, the decision to have an MRI will be based on the clinical need as determined by the patient's ordering physician. Candidates must have a strong clinical indication for the scan, where MRI is the diagnostic modality of choice for a specific disease state without acceptable alternative imaging technology as judged by the ordering physician.

The protocol requires the participation of a cardiologist with a working knowledge of pacemaker and ICD function who is capable of device interrogation and programming (with the assistance of an industry device representative). Patients will have their device interrogated immediately before the scan, and the device will be reprogrammed appropriately. The patient will remain on a cardiac monitor with a physician present throughout the scan. Immediately following the MRI, the device will be re-interrogated and initial parameters restored. The incidence of adverse events or changes in device parameters between pre- and post-MRI interrogations and follow-up interrogations will be recorded. Reimbursement will be provided for the physician participation during the MRI procedure and completing follow-up device interrogations.

The protocol is performed as an investigator-initiated study with multiple sources of funding (competitive grants, foundation fellowship support, industry grants and philanthropy). The results of this registry may be used to establish guidelines for the use of clinically-indicated, non-thoracic MRI for patients with implanted cardiac devices.



Inclusion Criteria

1. Male or female 18 years or older
2. Permanent pacemaker or ICD generator implanted after 2001
3. Strong clinical indication for MRI
4. Scheduled for non-thoracic MRI

Exclusion Criteria

1. Metallic objects that are a contraindication to MRI
2. Claustrophobia unresponsive to oral sedatives
3. Morbid obesity (abdominal diameter >60 cm)
4. Has an ICD and is pacing dependent
5. Pregnancy
6. Battery voltage at ERI
7. Active implanted device (other than pacemaker/ICD)
8. Presence of abandoned leads
9. Cardiac device in abdominal position.
10. Pacemaker or ICD that is labeled as MRI-Conditional (approved by the FDA for exposure to MRI).