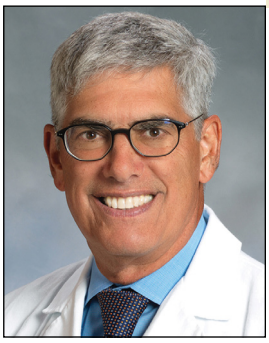
SPOTLIGHT ON CLINICAL RESEARCH

ICD Therapy, Heart Failure, Amyloidosis, In-Stent Restenosis

Heather Madara
Supervisor Research Regulatory and Outreach
Roy S. Small, MD
Medical Director of Clinical Research
Penn Medicine Lancaster General Health Research Institute


Madara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Editor's note: Physicians who wish to refer patients for any of the studies mentioned below are encouraged to contact the Research Institute at 717-544-1777. Other members of the LG Health staff who are conducting research and wish to have their studies described here are encouraged to contact the offices of JLGH at 717-544-8004.

SPONSORED STUDIES

ASCEND CSP IDE: A Stylet-Driven ICD Lead Intended for Conduction System Pacing IDE Study

Sponsor: Abbott
Principal Investigator: Matthew Bernabei, MD

This is a single-arm study aimed at evaluating the safety and effectiveness of the investigational conduction system pacing (CSP) implantable cardioverter-defibrillator (ICD) lead. This lead, created by Abbott, is implanted along with an ICD or cardiac resynchronization therapy device (CRT-D) that provides ICD therapy. The ICDs and CRT-Ds used in the study are FDA approved, but the ICD lead is not yet approved and is considered investigational.

Scan to learn more about the ASCEND CSP IDE study.

The study will evaluate the ICD lead in patients who already meet the indication to receive ICD or CRT-D therapy. Once enrolled, participants will undergo an implant procedure and complete study follow-up activities for approximately 18 months, including standard six-month device checks until the end of the study.

LG Health was activated as a study site in September 2025 and plans to enroll about 12 patients.

ELEVATE-HFpEF: Randomized Trial of ELEVATEd Cardiac Pacing Rate for Personalized Treatment of Heart Failure With Preserved Ejection Fraction

Sponsor: Medtronic
Principal Investigator: Amit Varma, MD

ELEVATE-HFpEF is a randomized, double-blind trial evaluating the safety and efficacy of dual-chamber personalized pacing in patients with heart failure with preserved ejection fraction (HFpEF). HFpEF is a common condition for which there are limited therapeutic options. Currently, HFpEF is not an approved indication for cardiac pacing.

However, preliminary evidence shows that cardiac pacing may have beneficial effects in the HFpEF population. The study plans to evaluate the effect of personalized pacing on the functional capacity of HFpEF patients. The pacing will be determined based on participants' left ventricle ejection fraction and height.

All participants will receive an FDA-approved Medtronic pacemaker. However, since the use of pacemakers is not indicated for HFpEF patients, its use in this study is considered investigational. The study team will randomize participants post-implant to receive either personalized pacing (treatment group) or no/minimal pacing (control group).

All participants will complete study follow-up visits at two months, six months, and 12 months post-implant. At the 12-month visit, the control group participants' pacemakers will be programmed with personalized pacing. Study visits will occur at 14 months, 18 months, and 24 months before transitioning to annual follow-ups until study completion.

The study team at LG Health, led by Dr. Amit Varma, plans to enroll about five participants. They received activation to begin enrolling in November 2025.

Scan to learn more about the ELEVATE-HFpEF study.

TRITON-CM: A Phase 3 Global, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Nucresiran in Patients With Transthyretin-Mediated Amyloidosis With Cardiomyopathy (ATTR Amyloidosis With Cardiomyopathy)

Sponsor: Alnylam Pharmaceuticals
Principal Investigator: Arpan Patel, DO

Alnylam Pharmaceuticals is sponsoring a Phase 3 double-blind clinical trial aimed at evaluating the safety and efficacy of nucresiran, a transthyretin silencer, in patients diagnosed with Transthyretin-Mediated Amyloidosis with Cardiomyopathy (ATTR Amyloidosis With Cardiomyopathy). The study will evaluate how effective nucresiran is by measuring the impact on all-cause mortality and cardiovascular events, as well as on patient-reported quality-of-life.

Eligible participants will be randomized 1:1 to receive the study drug or placebo. They will be in the study for five to eight years, depending on when they join the study. The first 32 months of participation comprise the double-blind treatment period. Following this period, all participants will receive nucresiran as part of the open-label extension period. Follow-up assessments aimed at determining the safety and efficacy of the study drug include, but are not limited to, echo, ECG, blood and urine tests, and quality-of-life questionnaires.

The LG Health study team plans to enroll 5-10 participants. They received activation from the sponsor to begin enrolling in January 2026.

← Scan to learn more about the TRITON-CM study.

PENN-LED SPONSORED STUDY

Prevail: A Randomized Controlled Study of the Prevail Drug-Coated Balloon in Subjects With In-stent Restenosis and a Single Arm Prospectively Enrolled Study of the Prevail Drug-Coated Balloon for de Novo Lesions in Small Vessel Disease

Sponsor: Medtronic
Local Principal Investigator: T. Raymond Foley, MD

The Prevail global study aims to evaluate the safety and efficacy of the Medtronic Prevail Drug-Coated Balloon (DCB), which is a paclitaxel coated balloon used in the treatment of in-stent restenosis. Participants are randomized to receive either the Prevail DCB, which is not FDA approved yet, or the Agent DCB, which is FDA approved.

Participants will not know which DCB they receive until the study ends. The study is anticipated to last for about six years; participants will be in the study for about five years.

← Scan to learn more about the Prevail study.

LG Health was invited to join this study alongside the Hospital of the University of Pennsylvania (HUP) as part of the One Penn Medicine One Research initiative. Taisei Kobayashi, MD, is serving as the primary principal investigator (PI) at HUP, with T. Raymond Foley, MD, serving as the LG Health PI and Russell Rosenberg, MD, serving as the PI at Penn Presbyterian. The study team at LG Health plans to enroll about 20 participants.

Heather Madara
Penn Medicine LG Health Research Institute, 133 E. Frederick St., Lancaster, PA 17602
Heather.Madara@pennmedicine.upenn.edu

Roy S. Small, MD
The Heart Group of LG Health, 217 Harrisburg Ave., Lancaster, PA 17603
Roy.Small@pennmedicine.upenn.edu