

CLINICAL TRIALS PORTFOLIO



BOOMBOX Master Study: The HistoSonics Edison System for Treatment of Primary and Metastatic Liver Tumors Across Multidisciplinary Users

NCT06486454

STUDY DESIGN: An observational, single-arm, non-randomized, prospective Master Protocol driven post market study designed to observe the use of histotripsy to treat primary and metastatic liver tumors

SAMPLE SIZE: Up to 5000 patients

POPULATION: Primary (e.g., HCC, cholangiocarcinoma, angiosarcoma) or metastatic (from other primary cancers) liver cancer, or benign liver tumors (e.g., adenoma)

PRIMARY OUTCOME MEASURE: The Master Protocol will evaluate technical success, defined as completion of histotripsy on the target tumor(s) according to the histotripsy treatment plan, assessed by the treating physician on CT or MR imaging at ≤ 36 hours post-histotripsy treatment. Hypotheses generated based on the data collected in the Master Protocol can be used to design follow on trials.

STATUS: Recruiting participants

CAIN: The HistoSonics Investigational System for Treatment of Primary Solid Renal Tumors Using Histotripsy.

NCT05432232

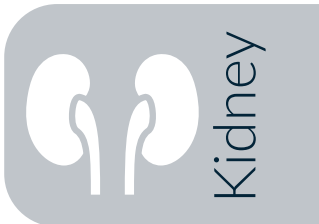
STUDY DESIGN: A prospective, multi-center, single-arm pilot trial designed to evaluate the effectiveness and safety profile of the HistoSonics Investigational System to treat solid renal tumors

SAMPLE SIZE: 20 participants

POPULATION: Patients with non-metastatic solid renal tumor ≤ 3 cm

PRIMARY ENDPOINTS: Technical success defined as complete coverage of the tumor as determined ≤ 36 hours post-index procedure and freedom from index procedure related major complications at 30 days after the last histotripsy procedure

STATUS: Completed



#HOPE4KIDNEY: The HistoSonics Edison™ System for Treatment of Primary Solid Renal Tumors Using Histotripsy

NCT05820087

STUDY DESIGN: Prospective, multi-center, single-arm pivotal trial designed to evaluate the effectiveness and safety of the HistoSonics Edison System for the destruction of kidney tissue by treating primary solid renal tumor

SAMPLE SIZE: 67 participants

POPULATION: Participants with a solitary non-metastatic solid renal tumor ≤ 3 cm

PRIMARY ENDPOINTS: Technique Efficacy: percentage of targeted tumors successfully eliminated after a single histotripsy assessed at 90 days. Safety: Freedom from index procedure related major complications at 30 days post procedure

STATUS: Enrollment completed in May 2025; active follow-up

The use of the HistoSonics Edison System in kidney applications is limited to investigational use only.

GANNON: The HistoSonics Edison™ System for Treatment of Pancreatic Adenocarcinoma Using Histotripsy

NCT06282809

STUDY DESIGN: A prospective multi-center, single-arm, feasibility trial designed to evaluate the safety of the HistoSonics Edison System for the destruction of pancreatic adenocarcinoma tumors in patients who are diagnosed with unresectable locally advanced (Stage 3) or oligometastatic disease (Stage 4)

SAMPLE SIZE: Up to 50 subjects, three cohorts based on planned histotripsy treatment size

POPULATION: Unresectable pancreatic adenocarcinoma, locally advanced (Stage 3) or oligometastatic disease (Stage 4). Patients must receive ≥8 weeks of chemotherapy prior to being considered for this trial

PRIMARY OUTCOME MEASURE: Index procedure-related complications ≤30 days post index procedure

STATUS: Recruiting participants



Pancreas

The use of the HistoSonics Edison System in pancreatic applications is limited to investigational use only.

WOLVERINE: The Edison System for Treatment of Benign Prostatic Hyperplasia (BPH) Using Histotripsy

NCT07214675

STUDY DESIGN: A prospective multi-center, single-arm, feasibility trial designed to evaluate the safety of the HistoSonics Histotripsy System for treatment of benign prostatic hyperplasia (BPH)

SAMPLE SIZE: Up to 80 participants

POPULATION: Participants who are 50 years of age or older with a diagnosis of BPH

PRIMARY OUTCOME MEASURE: Index procedure-related complications ≤30 days post index procedure

STATUS: Recruiting participants



Prostate

The use of the HistoSonics Edison System in prostate applications is limited to investigational use only.

The Edison® System is intended for the non-invasive mechanical destruction of liver tumors, including the partial or complete destruction of unresectable liver tumors via histotripsy. The FDA has not evaluated the Edison System for the treatment of any disease including, but not limited to, cancer or evaluated any specific cancer outcomes (such as local tumor progression, 5-year survival or overall survival). The System should only be used by persons who have completed training performed by HistoSonics, and its use guided by the clinical judgment of an appropriately trained physician. Refer to the device Instructions for Use for a complete list of warnings, precautions and a summary of clinical trial results, including reported adverse events.