INTRODUCTION & OBJECTIVES: To evaluate the feasibility, adverse event profile, functional outcome and efficacy of focal irreversible electroporation (IRE) for pT1a renal cell carcinoma (RCC) in consecutive patients of the first prospective, monocentric Phase 2a pilot ablate-and-resect study (IRENE trial). For this new technology a complete ablation of soft-tissue tumors with protection of healthy peritumoral tissue and anatomical structures has been postulated.

MATERIAL & METHODS: Approval for this GCP-compliant study [NCT01967407 (10/2013)] was granted by the German Federal Institute for Drugs and Medical Devices BfArM (CIV-12-4-006021) and authorized ethics [73/2012]. 7 patients (mean age 68 y; ECOG 0-2; Charlson Score 0-2) with biopsy proven RCC pT1a cN0cM0 (5/7 clear-cell, 2/7 papillary; located cortically 5/7 and centrally 2/7) with a mean tumor size of 22 mm (range 15-39) underwent percutaneous CT-guided (Aquillion prime CT scanner, Toshiba, USA) IRE (NanoKnife system, AngioDynamics, USA). IRE was performed ECG-triggered in general anaesthesia and deep muscle paralysis with 3-6 monopolar electrodes positioned within the renal tumor (90 µs pulse length; 2-4 ablations per tumor in 1 session). At 28 days after IRE the tumor region was completely resected surgically. A contrast-enhanced, diffusion-weighted MRI was carried out 1 day before as well as 2, 7, 27 and 112 days after IRE. Clinical parameter, quality of life, pain feeling and complications were recorded 1 day before as well as 1, 2, 7, 27, 29, 30, 35 and 112 days after IRE. Restaging CT was ensued 6 and 12 month after IRE, then annually.

RESULTS: Technical feasibility was achieved in all patients, but electrode placement and ablation was complex with mean overall procedure time of 129 min and anaesthesia time of 165 min. There were no major or residual procedure-related complications. Minor complications occurred including slight self-limiting macrohematuria (7/7), perirenal hematomas (2/7) and drug-treated temporary post-puncture pain (7/7). In all cases MR imaging demonstrated a complete coverage of the tumor area by the ablation zone, nearly size persistent tumor areas with contrast enhancement but degenerative change of hypoperfusion and diffusion restriction. Intrasurgically examinations showed severe local perirenal adhesions. Renal function after IRE was retained in all cases with no urinary leakage or retention, no renal infarction and no significant change of creatinine. Partial kidney resection was performed in 5 of 7 patients and radical nephrectomy in 2 of 7 due to central tumor ablation areas. Resection exhibited in 4/7 cases ypT0V0N0Pn0R0; and 3/7 cases with ypT1aV0N0Pn0R1 due to small residual tumor areas.
with viable tumor cells in 2 cases and uncertain viable tumor cells in 1 case. Mean follow-up of 25 month had no evidence of local recurrence or metastasis.

**CONCLUSIONS:** Renal percutaneous NanoKnife IRE appears to be a safe treatment for small renal tumors but needs a high procedural effort. According to these initial study results the curative intended, renal saving focal ablation of T1a RCC appears to be possible, but needs further technical improvement and evaluation for a certain complete ablation by this still experimental method.