

SPYRAL HTN-OFF MED PIVOTAL



AMERICAN COLLEGE of CARDIOLOGY

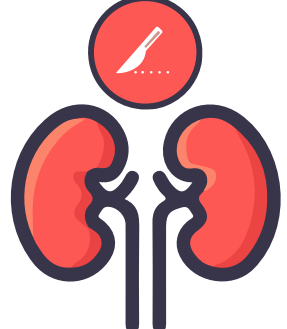
Efficacy of catheter-based renal denervation in the absence of antihypertensive medications

Multicenter, randomised, sham-controlled trial

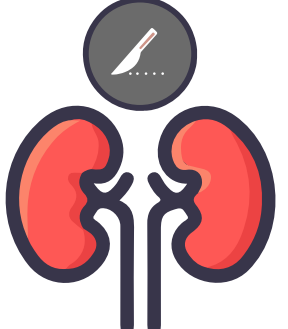
 **Objective:** To assess the efficacy of renal denervation in the absence of antihypertensive medications.

331
patients

Inclusion criteria: Patients aged 20-80 years, history of hypertension with office systolic blood pressure of 150 mm Hg to less than 180 mm Hg were randomly assigned 1:1 to following groups:

 **Renal denervation**
(n=166)

VS

Sham procedure
(n=165) 

PRIMARY OUTCOME

-4.7

Baseline-adjusted change in 24-hour systolic BP (mm Hg)
P=0.0005

-0.6

SECONDARY OUTCOME

-9.2

Baseline-adjusted change in office systolic BP from baseline to 3 months (mm Hg)
P<0.0001

-2.5

No major device-related or procedural-related safety events occurred up to 3 months.

Conclusion: SPYRAL Pivotal showed the superiority of catheter-based renal denervation compared with a sham procedure to safely lower blood pressure in the absence of antihypertensive medications alone.

Böhm M, Kario K, Kandzari DE, et al. Efficacy of Catheter-Based Renal Denervation in the Absence of Antihypertensive Medications (SPYRAL HTN-OFF MED Pivotal): a Multicentre, Randomised, Sham-controlled Trial. Lancet; Mar 29:[Epub ahead of print].