

# Longer Term Safety and Efficacy of Sympathetic Renal Artery Denervation using a Multi-Electrode Renal Artery Denervation Catheter in Patients with Drug-Resistant Hypertension: Eighteen Month Results of a First-in-Human, Multicenter Study

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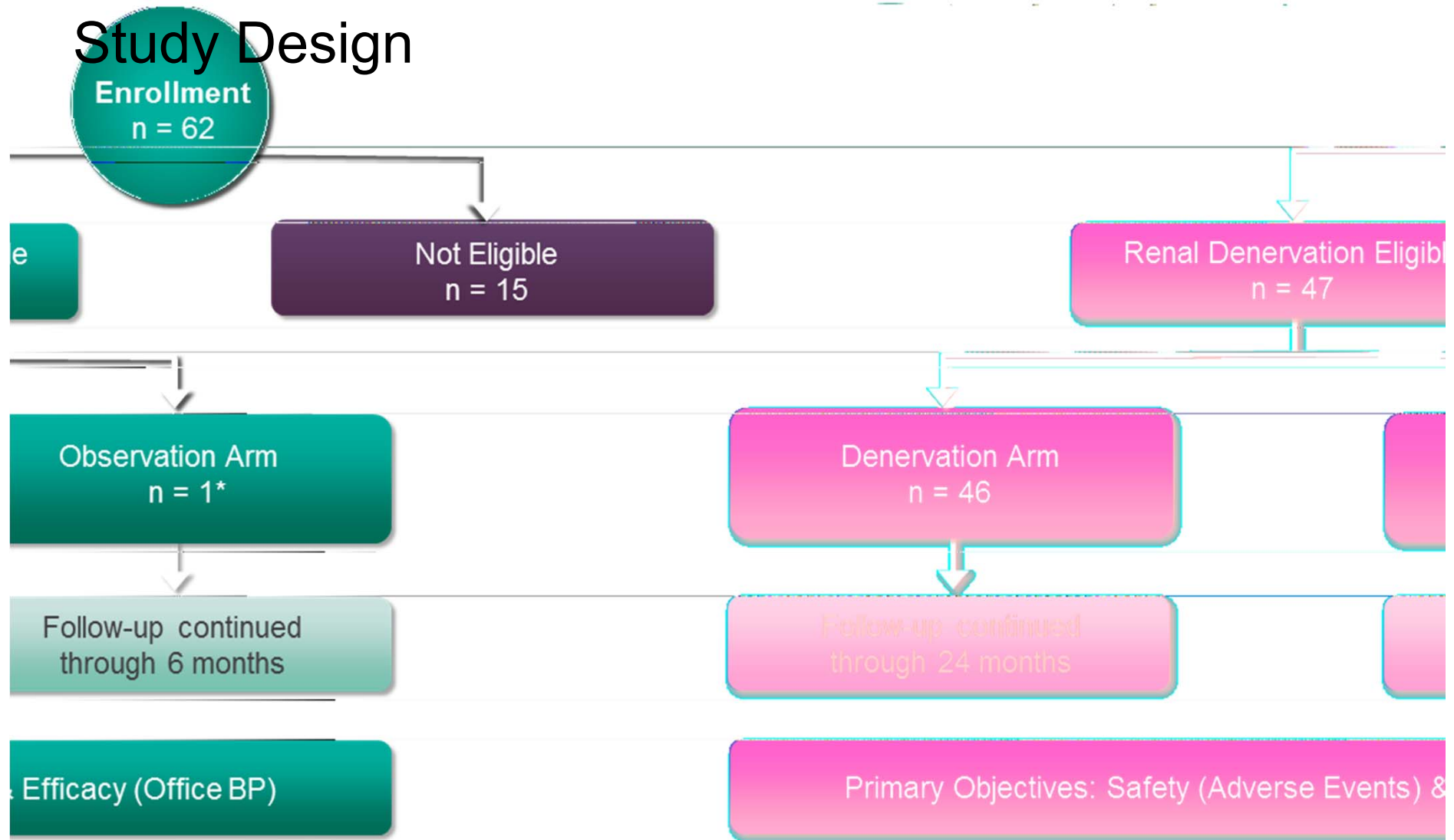
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# Study Design



\* Exclusion due to renal artery anatomy therefore renal denervation was not attempted.

# Study Results: Safety Data

## Objective

The primary safety outcome was assessment of all adverse events.

- **No Serious Peri-Procedural Events**
- **Serious device/procedure events through 18 months:**
  - Worsening of pre-existing proteinuria (n=1)
  - Symptomatic hypotension (n=1)
  - Worsening of pre-existing renal artery stenosis and new stenotic lesion (n=2 events in 1 patient)

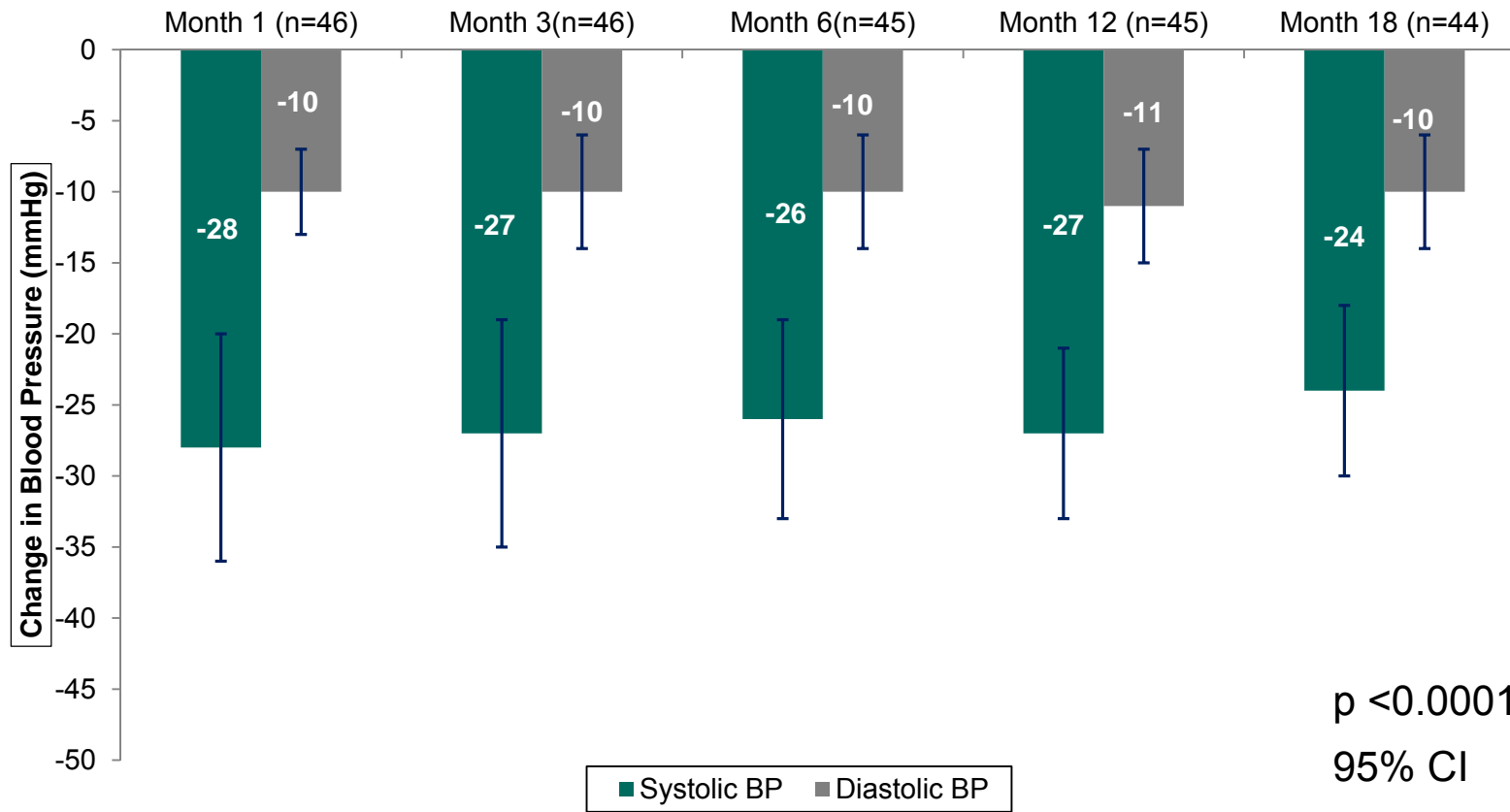
**The EnligHTN System delivers renal denervation with no serious peri-procedural events and an acceptable safety profile through 18 months**

# Study Results: Renal Function

	Baseline (n=46)	Month 1 (n=46)	Month 3 (n=46)	Month 6 (n=45)	Month 12 (n=45)	Month 18 (n=44)
eGFR (mL/min/1.73m <sup>2</sup> )	87 (±19)	85 (±20)	84 (±22)	82 (±20)	86 (±21)	77 (±16)
Serum Creatinine (mmol/L)	78 (±17)	79 (±19)	81 (±20)	83 (±20)	80 (±28)	86 (±21)
Cystatin C (mg/L)	1.14 (±0.29)	1.00 (±0.25)	0.97 (±0.20)	1.00 (±0.23)	0.91 (±0.19)	1.1 (±0.3)
Urine Albumin- to-Creatinine Ratio (mg/g)	167.6 ± 493	142.9 (±477)	141.3 (±449)	139.3 (±449)	116.9 (±421)	131.0 (±358)

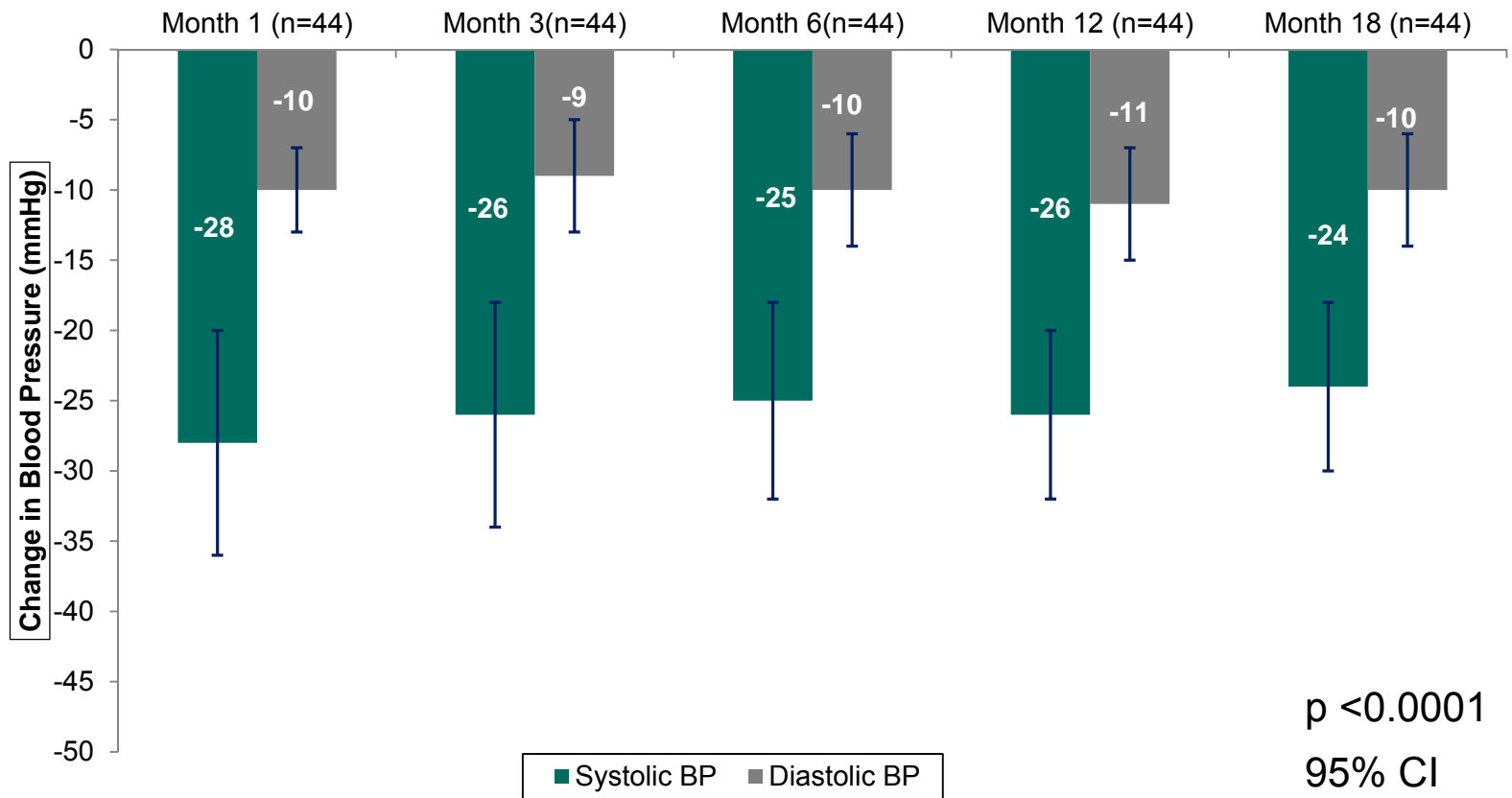
**No clinically significant changes in renal function.**

# Office BP Reduction from Baseline



**EnligHTN therapy delivers a rapid and significant reduction in Office BP that is sustained through 18 months**

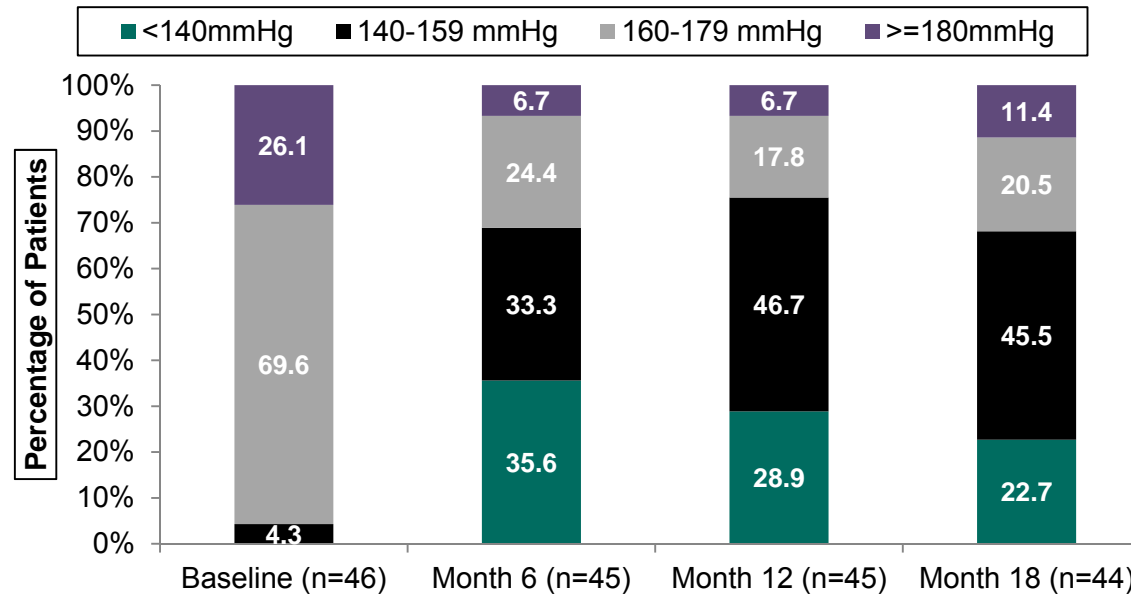
# Office BP Reduction from Baseline



*EnlighTN therapy delivers a rapid and significant reduction in Office BP that is sustained through 18 months*

# Responder & Goal Blood Pressure Parameters

- 77% of patients are considered responders at 18 months (>10 mmHg OSBP Reduction from baseline)
- 68% have an OSBP <160 mmHg at 18 months despite a mean baseline of 176 mmHg



*~2/3 of patients have a great enough reduction in their BP to move to a lower stage of HTN classification and treatment*

# EnligHTN I 18 Month Results

## Safety

- No serious peri-procedural events
- No flow-limiting renal artery vasospasms

## Short Term Results

- Office BP was reduced by 28/10 mmHg at one month

## Long Term Results

- A significant reduction in office Systolic and Diastolic BP was sustained at 18 months
- 77% of patients are responders at 18 months