UMC Utrecht

Baroreceptor activatie therapie is NIET de oplossing voor therapieresistente hypertensie

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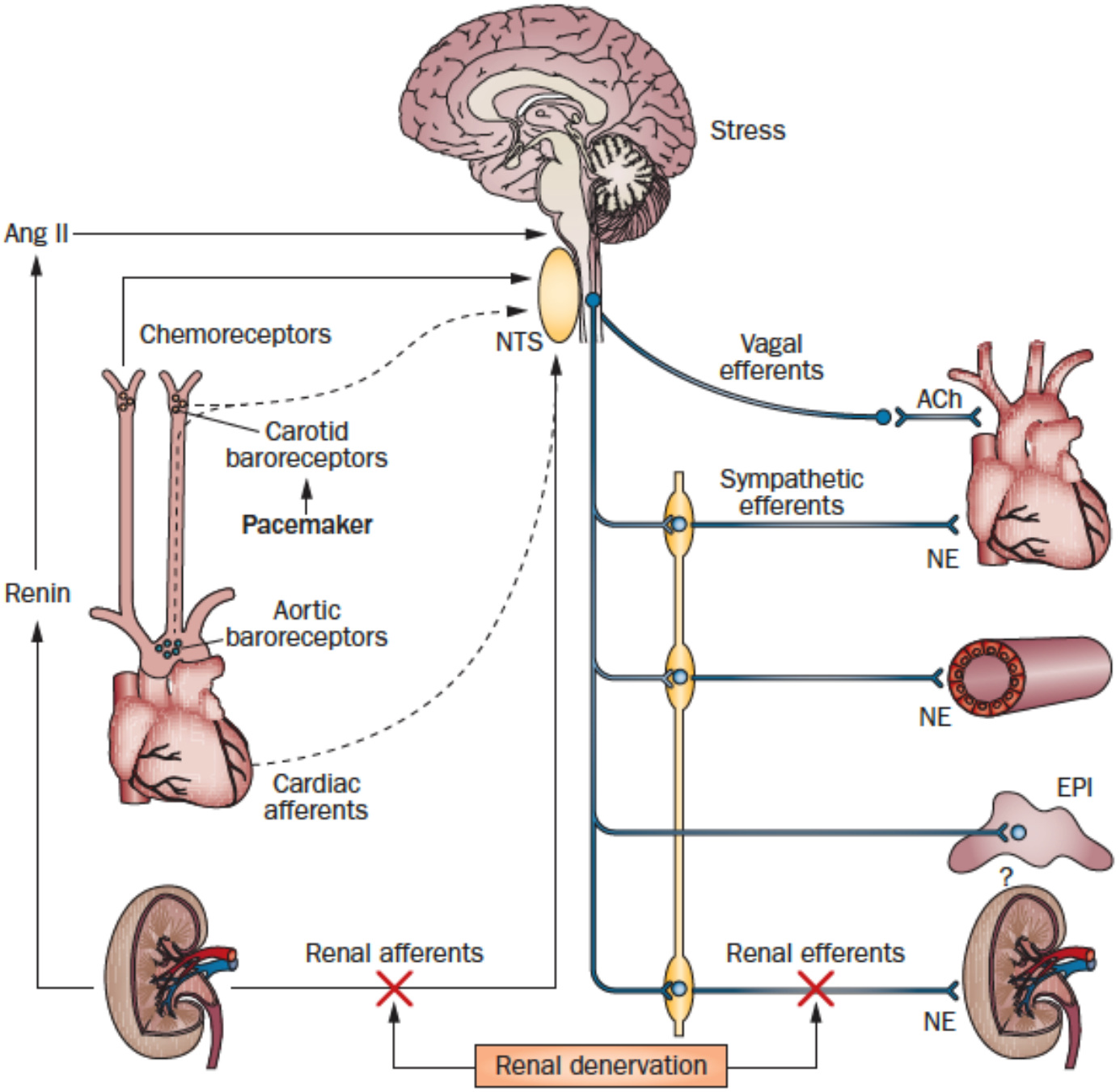
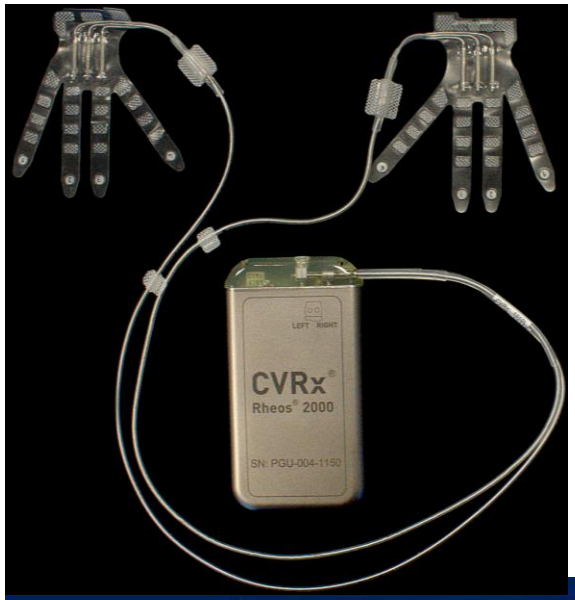
Disclosure potential conflicts of interest

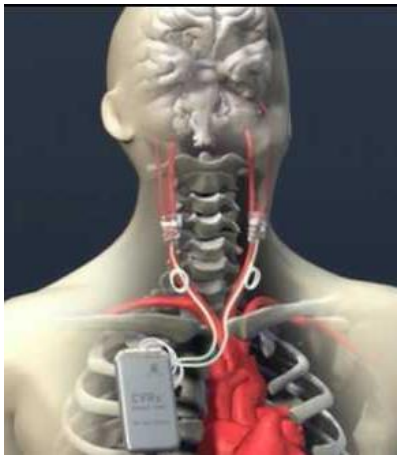
Research contracts:	Innovatiefonds Zorgverzekeraars
Consulting:	Vascular Dynamics, Inc.
Employment in industry:	-
Stockholder of a healthcare company:	-
Owner of a healthcare company:	-
Other:	Voorzitter Internistisch Vasculair Genootschap Secretaris Nederlandse Hypertensie Vereniging

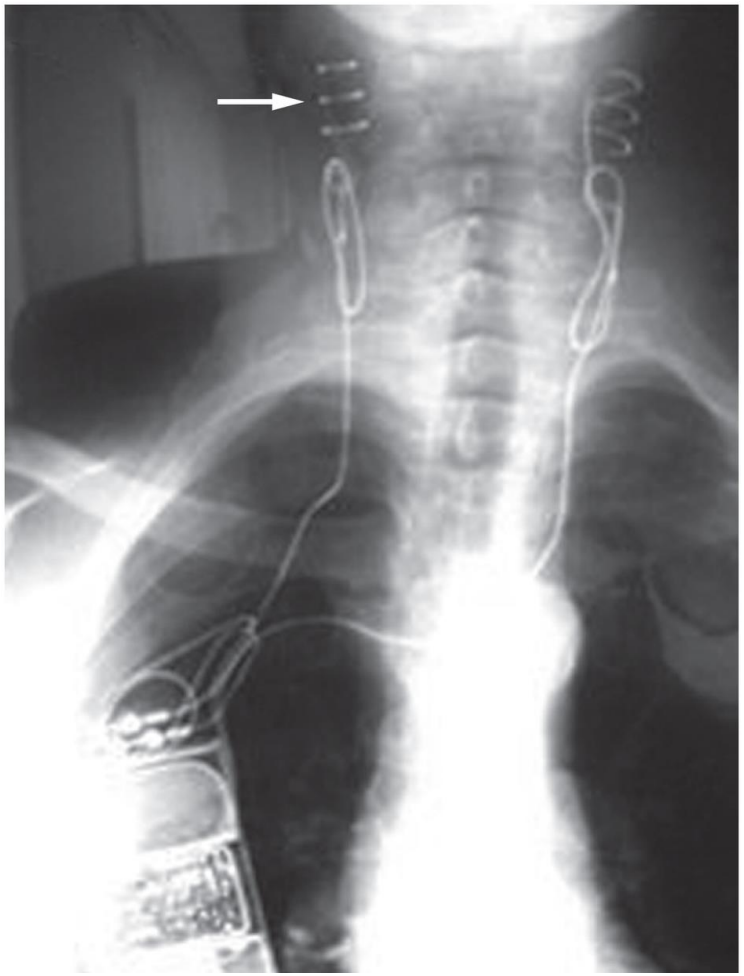


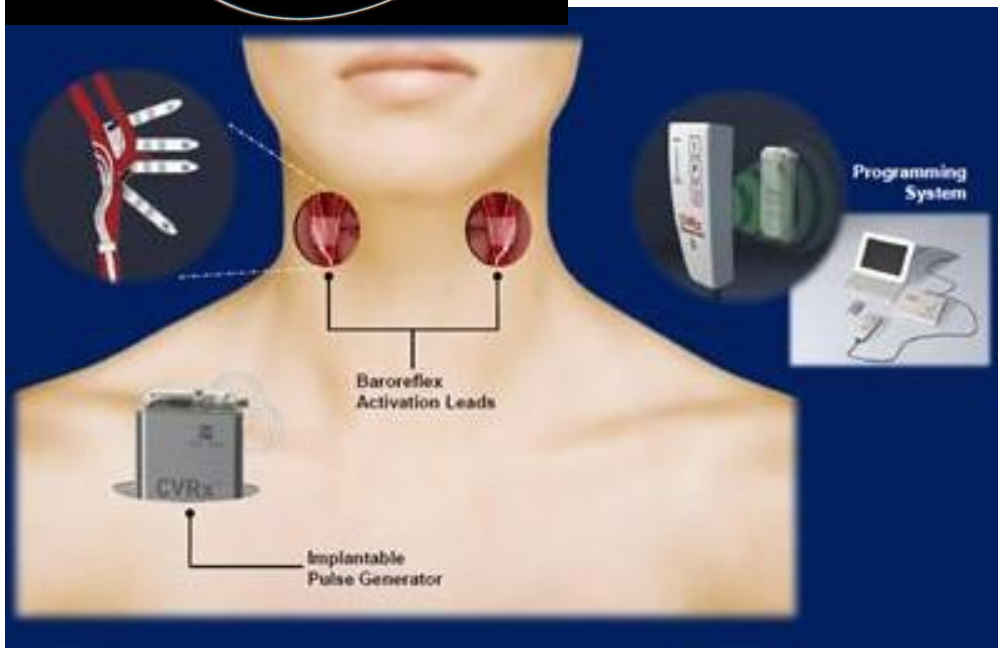
Shafiq, Curr Hypertens Rep, 2008

CVRx Rheos system

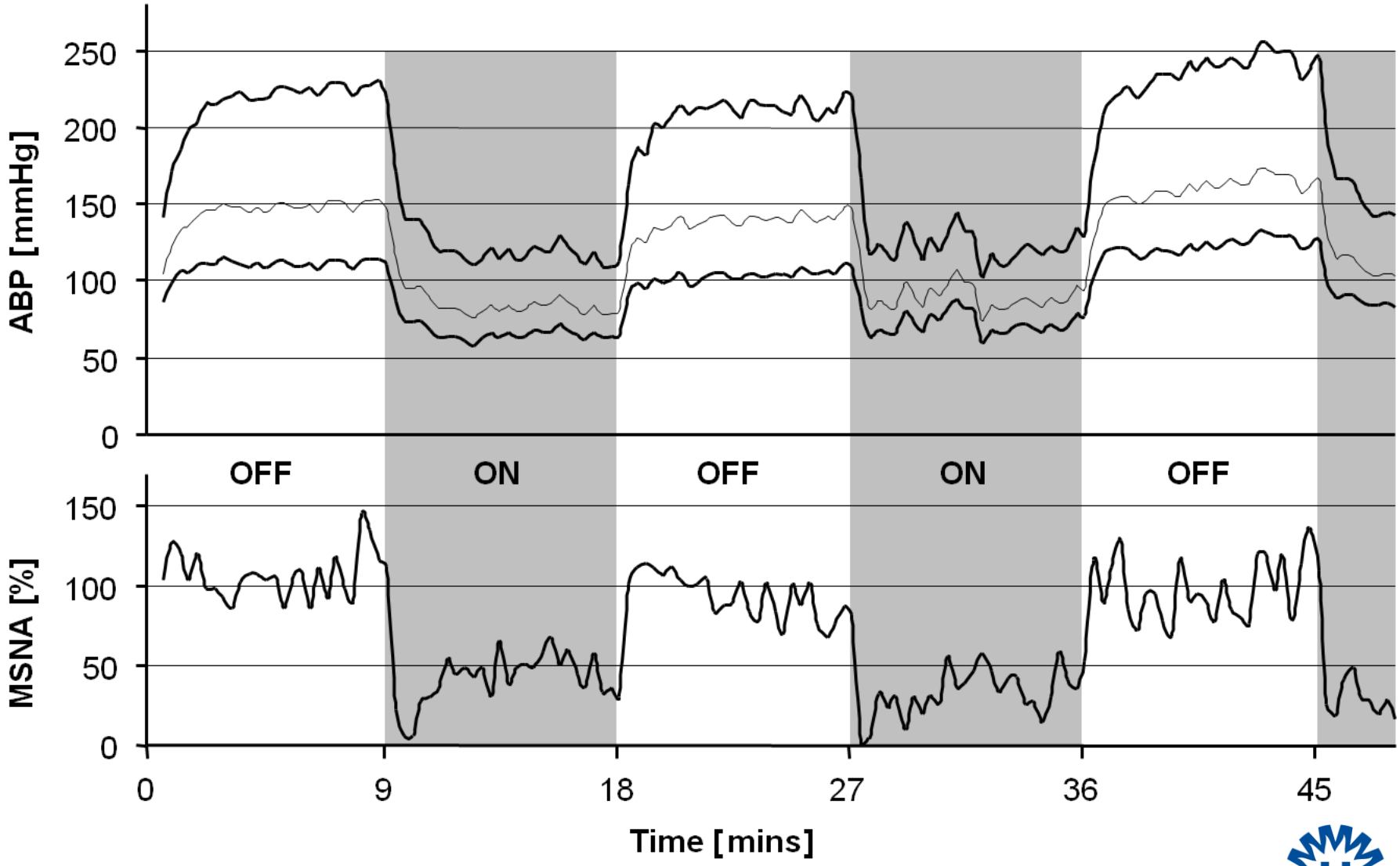








Mechanism of action

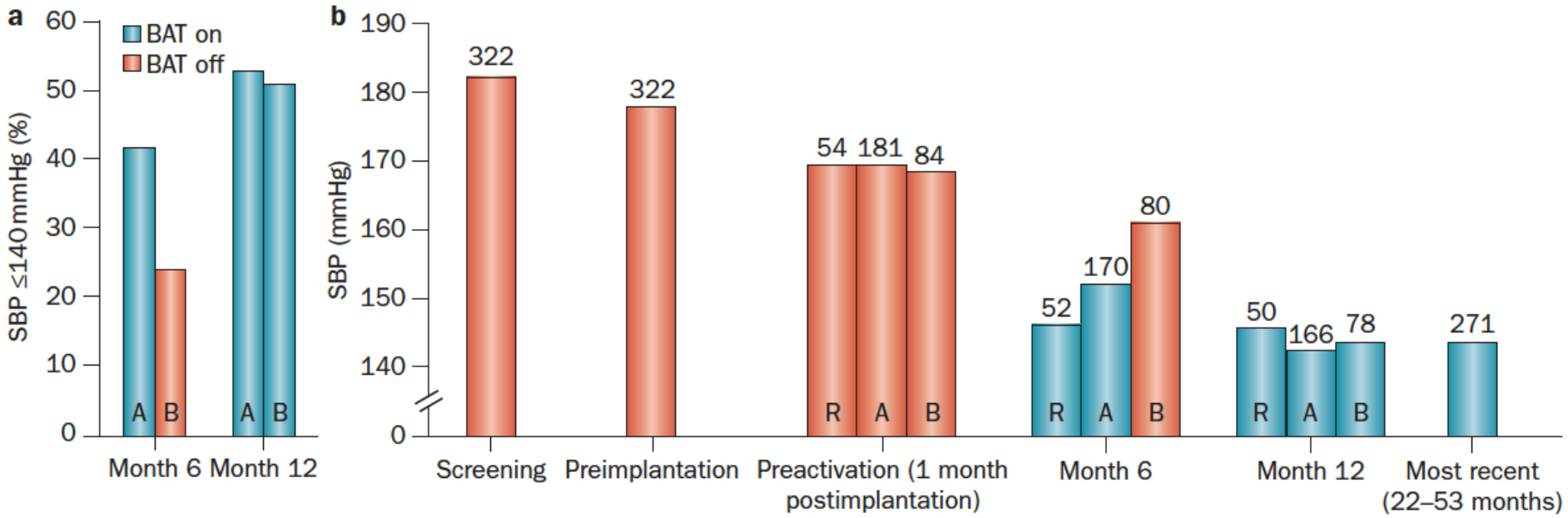


Rheos Pivotal Trial: design

- Evaluation efficacy and safety of BAT (with Rheos) in resistant hypertension
- Double-blind, randomized, prospective, multicenter, placebo-controlled
- 2:1 randomization to immediate (n=181) or delayed (n=84) BAT
- 5 coprimary endpoints:
  - Acute SBP responder rate at 6 months
  - Sustained responder rate at 12 months
  - Procedure safety
  - BAT safety
  - Device safety
- Sponsor: CVRx, Inc.

Bisognano, J Am Coll Cardiol, 2011

Rheos Pivotal Trial: BP responses



Bisognano, J Am Coll Cardiol, 2011

Rheos Pivotal Trial: efficacy and safety

- Efficacy:
  - Acute SBP responder rate at 6 months ✗
  - Sustained responder rate at 12 months ✓
- Safety:
  - Procedure safety ✗
  - BAT safety ✓
  - Device safety ✓

Barostim *neo* clinical data

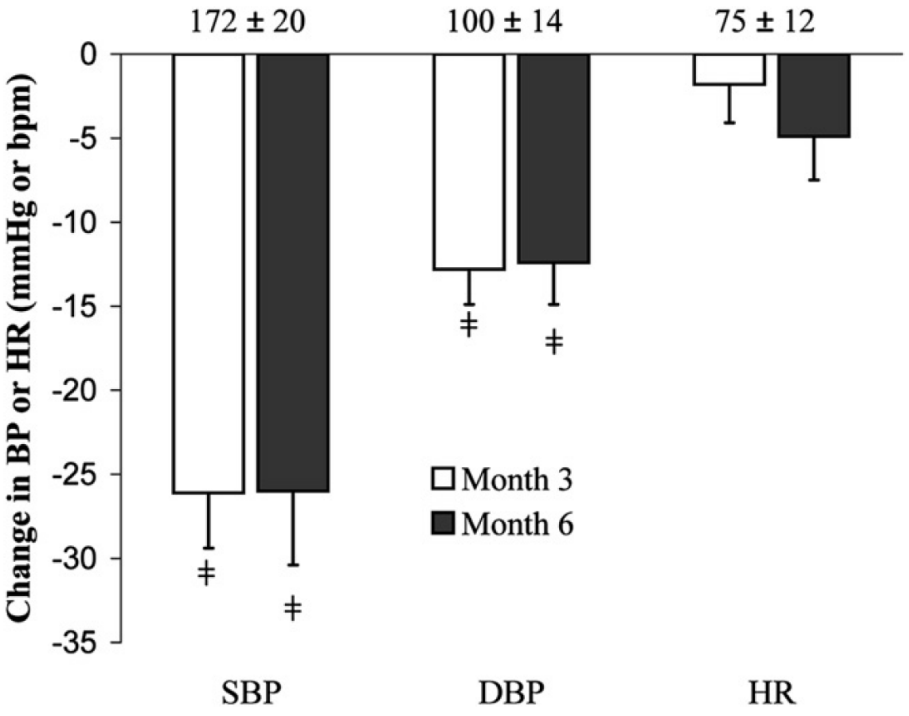
Study	n	Indication	Design	Reference
Barostim neo Trial	30	Resistant hypertension	Observational, multicenter, open label, cohort study	Hoppe, J Am Soc Hypertens 2012
BAT on arterial stiffness and central hemodynamics	25	Resistant hypertension	Observational, single center, open label, cohort study	Wallbach, J Hypertens 2015
BAT in heart failure: proof of concept	11	Heart failure	Observational, single center, open label, cohort study	Gronda, Eur J Heart Fail 2014
Barostim Neo System in the Treatment of Heart Failure	146	Heart failure	Randomized, controlled, multicenter, open label, trial	Abraham, JACC Heart Fail 2015

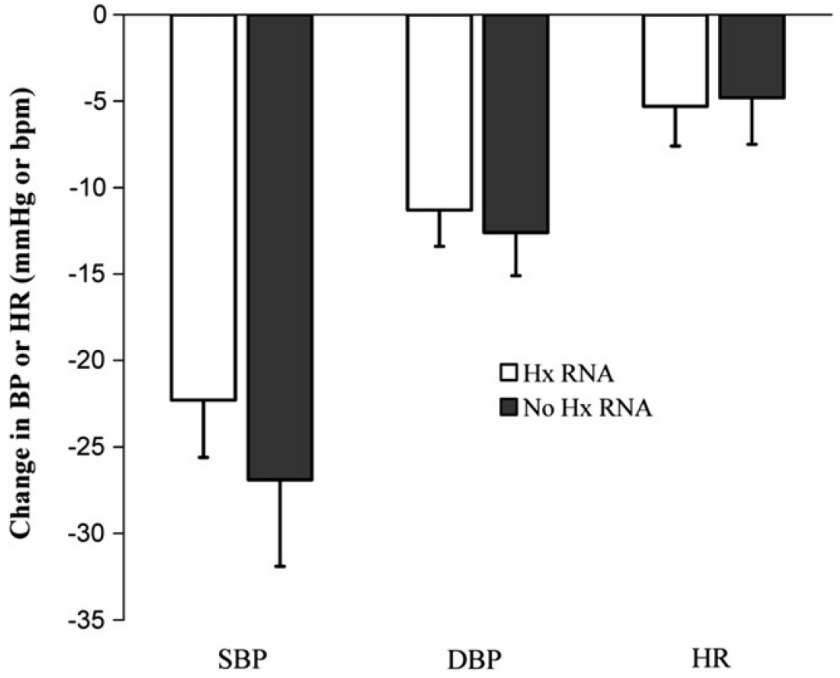
Barostim *neo* Trial: design

- Evaluation safety and efficacy of BAT (with Barostim *neo*) in resistant hypertension
- Non-randomized, multicenter, open label
- n=30
- Primary endpoints:
  - Safety at 6 months
  - Office SBP at 6 months
- Sponsor: CVRx, Inc.

Hoppe, J Am Soc Hypertens, 2012

Barostim *neo* Trial: results





Hoppe, J Am Soc Hypertens, 2012

Barostim Hypertension Pivotal Trial: design

- Evaluation efficacy and safety of BAT (with Barostim *neo*) in resistant hypertension
- Randomized, prospective, multicenter, open label
- 1:1 randomization to BAT (and optimal medical therapy) or optimal medical therapy alone
- 310 patients
- 2 coprimary endpoints:
  - Safety at 1 month
  - Office SBP at 6 months
- Sponsor: CVRx, Inc.

Clinicaltrials.gov NCT01679132

Rheos vs. Barostim *neo*

- -26 mmHg (sham -17 mmHg) vs. -26 mmHg
- n=265 (RCT) vs. n=55 (non-randomized)
- FU up to 4 years vs. 6 months
- Peri-operative event-free 75% vs. 90%
- Long-term event-free 87% vs. 97%

BAT: de nadelen

- Chirurgie noodzakelijk
- Risico op zenuwbeschadiging
- Mapping met electrode noodzakelijk
- Duur (~€ 30.000 voor eerste implantatie)
- Pacemaker moet elke 3-5 jaar vervangen worden
- Geen vergoeding

Conclusies

- Niet bewezen effectief
- Lijkt veilig (Barostim *neo*)
- Meeste klinische data van systeem dat niet meer bestaat
- Duur
- Geen vergoeding


Vascular Medicine Utrecht