

Clinical Drug Investigation

Riociguat for the treatment of Raynaud's phenomenon: A single-dose, double-blind, randomized, placebo-controlled cross-over pilot study (DIGIT)

Michael Huntgeburth¹ · Johannes Kießling¹ · Gerrit Weimann² · Verena Wilberg³ · Soundos Saleh² · Nicolas Hunzelmann^{4*} · Stephan Rosenkranz^{1,5*}

¹ Clinic III for Internal Medicine, Department of Cardiology, Heart Center, University Hospital of Cologne, Germany

² Bayer AG, Berlin, Germany

³ ClinStat GmbH, Cologne, Germany

⁴ Department of Dermatology, University of Cologne, Germany

⁵ Cologne Cardiovascular Research Center (CCRC), Heart Center, Cologne, Germany

Supplementary material

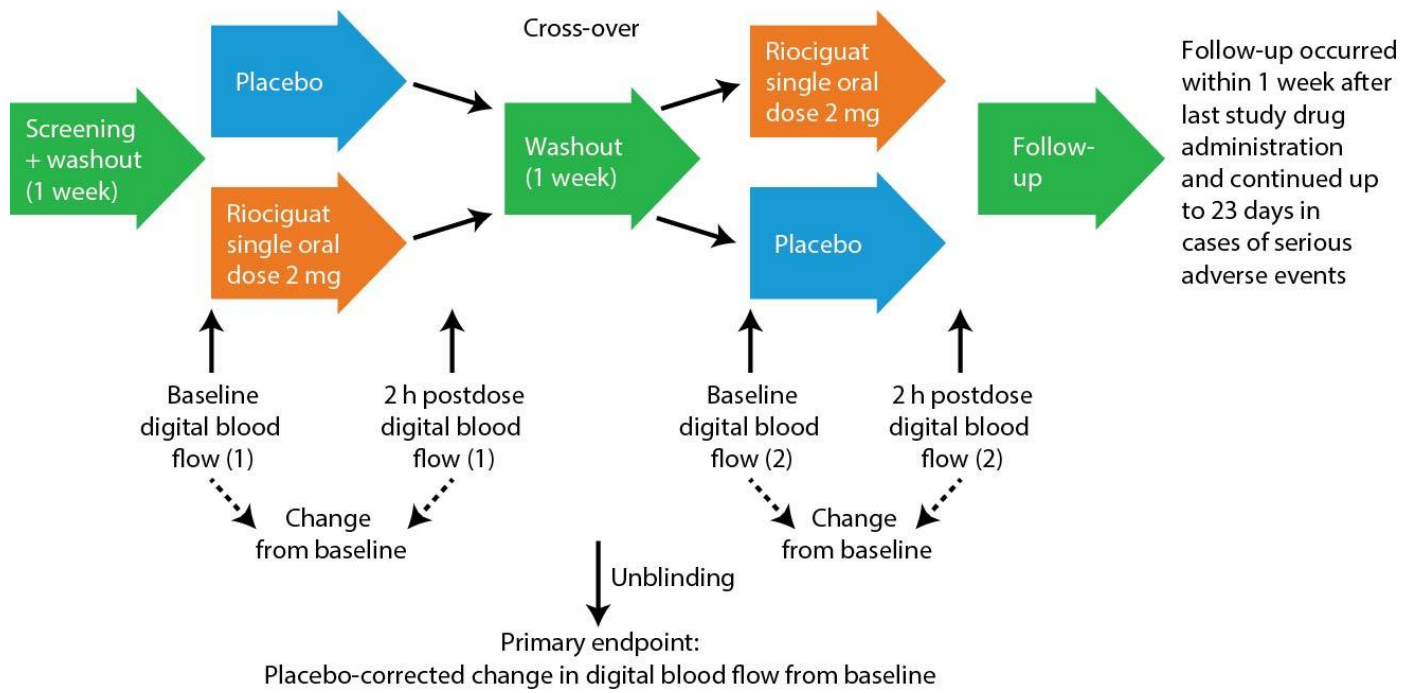
Supplementary Table 1 Vital signs following riociguat administration

Time from study drug administration, h	SBP/DBP (mmHg)		Heart rate (bpm)	
	Riociguat 2 mg (n = 20)	Placebo (n = 20)	Riociguat 2 mg (n = 20)	Placebo (n = 20)
-0.5 (baseline)	126/79	123/78	72	72
1	121/77	124/78	73	73
2	120/76	125/78	73	74
3	120/76	124/77	73	74
4	121/75	126/78	74	74

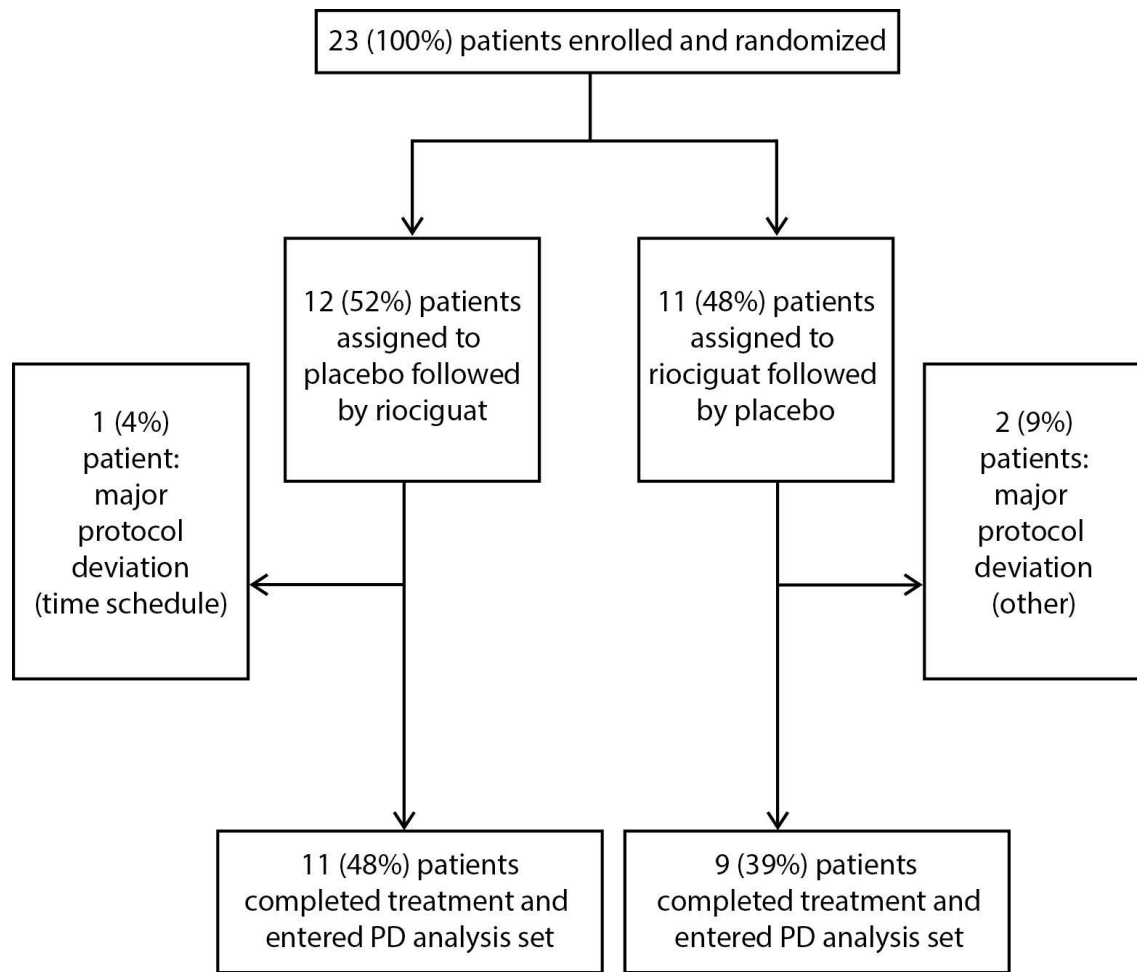
Data are mean values

bpm beats per minute, *DBP* diastolic blood pressure, *SBP* systolic blood pressure

Supplementary Fig. 1 DIGIT study design



Supplementary Fig. 2 Patient disposition in DIGIT



PD pharmacodynamic