

THE LANCET

Diabetes & Endocrinology

Supplementary appendix

This appendix formed part of the original submission and has been peer reviewed. We post it as supplied by the authors.

Supplement to: Parvanova A, Trillini M, Podestà M A, et al. Moderate salt restriction with or without paricalcitol in type 2 diabetes and losartan-resistant macroalbuminuria (PROCEED): a randomised, double-blind, placebo-controlled, crossover trial. *Lancet Diabetes Endocrinol* 2017; published online Nov 2. [http://dx.doi.org/10.1016/2213-8587\(17\)30359-5](http://dx.doi.org/10.1016/2213-8587(17)30359-5).

Supplementary Methods

Diet prescription and monitoring

The nutrient composition was flexible to accommodate individual preferences, but was designed to provide 45-50% of energy from carbohydrates, 30-35% from fat and 15-20% from proteins and to supply 100% of the daily recommended micronutrient intake, >20 g/day of fibres, and <300 mg/day of cholesterol to all study patients, independent of sodium diet allocation.⁷ No particular life-style modification was introduced. Every month dietary adherence was verified by a dietician and natriuresis was measured in 24-hour urine collections. Salt intake goals were set together with the patients and in order to facilitate adherence, patient-dietician contact (in person, by telephone, or e-mail) was provided throughout the study period at each monthly evaluation of natriuresis and whenever deemed appropriate.

Additional measurements

Samples were collected for possible explanatory analyses to be considered *a posteriori* to assess mechanisms possibly mediating the albuminuria/lowering effect, if any, of study treatments. Parameters considered for these potential, additional analyses included markers of the renin angiotensin system activity (plasma renin activity, plasma renin and pro-renin, angiotensin-II and aldosterone levels, 24-h urinary aldosterone excretion), brain natriuretic peptide (BNP) levels and markers of inflammation (serum C Reactive Protein levels, 24 hour urinary MCP-1, TGF Beta, and RANTES excretion). Pulse wave velocity and other markers of vascular stiffness were recorded, but were not analysed because of lack of treatment effect on pulse pressure (an indirect marker of vascular stiffness). For further details see study protocol at: http://clintrials.marionegri.it/images/Trials/protocol_proceed.pdf, (accessed Sept 8, 2017).

Supplementary Results

PARICALCITOL VS PLACEBO ACCORDING TO STUDY PERIOD – With low-sodium diet, albuminuria significantly decreased with both paricalcitol and placebo during the first study period (that is after randomisation, in parallel with sodium intake reduction). The opposite changes in albuminuria observed during the first study period between the two sodium intake groups on placebo ($p<0.01$) were fully blunted by paricalcitol (Supplementary Figure 2). During the second study period (that is after the cross-over, with patients on stable low or high-sodium intake), albuminuria did not change appreciably on placebo and showed a similar trend to decrease with paricalcitol in both diet groups. Changes in albuminuria (and in 24-hour UACR: data not shown) were significantly different between paricalcitol and placebo ($p<0.05$) in the low-sodium diet group (Supplementary Figure 2).

Supplementary Table 1. Primary and secondary outcomes according to sodium arms at baseline and different time points on follow up

	Baseline		Month 1		Month 2		Month 3	
	High Sodium	Low Sodium	High Sodium	Low Sodium	High Sodium	Low Sodium	High Sodium	Low Sodium
Weight (Kg)	84.9 (17.1)	91.1 (15.2)	84.1 (17.6)	89.7 (14.6)**	84.6 (17.1)†	89.5 (14.6)**	84.7 (17.5) ††	89.3 (14.1)**
24-hours BP recordings								
Systolic (mmHg)	144.7 (12.0)	147.9 (11.9)	143.2 (11.7)	143.1 (12.6)**	144.0 (12.1)	143.8 (13.4)**	144.9 (11.6)	143.4 (13.8)**
Diastolic (mmHg)	78.8 (5.6)	80.6 (6.2)	78.6 (6.2)	78.3 (5.7)**	78.8 (6.4)	79.1 (5.7)	80.0 (6.8)	78.8 (5.7)**
Mean (mmHg)	100.4 (6.5)	102.7 (7.3)	99.4 (7.7)	99.5 (7.4)**	100.2 (7.1)	100.3 (7.9)*	101.3 (7.3)	99.5 (6.0)**
Laboratory parameters								
HbA _{1c} (mmol/mol)	57.6 (15.9)	59.0 (12.9)	58.0 (15.7)†	57.3 (12.6)**	57.9 (17.2)	56.1 (13.4)*	58.6 (16.7)††	55.0 (13.4)**
Serum Glucose (mg/dL)	157.5 (60.6)	149.1 (44.4)	168.0 (69.1)	150.0 (53.9)	168.9 (64.7)*	147.9 (40.3)	166.3 (69.6)*	140.5 (38.4)
Total cholesterol (mg/dL)	175.8 (37.4)	169.4 (40.8)	179.3 (40.3)	167.2 (42.0)	178.2 (36.6)†	160.1 (32.5)	179.1 (38.2)†	160.3 (35.2)
HDL cholesterol (mg/dL)	45.3 (13.8)	41.7 (10.9)	45.2 (13.6)	40.6 (9.1)	45.9 (13.3)	40.3 (9.5)	46.5 (13.3)†	41.0 (9.5)
Triglycerides (mg/dL)	156.6 (106.0)	171.0 (109.9)	168.9 (149.9)	191.3 (177.9)	165.3 (109.2)	153.7 (89.1)	153.7 (97.6)	153.9 (80.2)
Calcium (mg/dL)	9.22 (0.32)	9.14 (0.35)	9.37 (0.40)**	9.35 (0.39)**	9.15 (0.31)	9.11 (0.33)	9.32 (0.44)*	9.34 (0.33)**
Phosphorus (mg/dL)	3.47 (0.50)	3.27 (0.53)	3.67 (0.55)**	3.54 (0.55)**	3.43 (0.54)	3.28 (0.57)	3.67 (0.50)**	3.56 (0.59)**
s. iPTH (pg/mL)	45.2 (22.7)	50.0 (21.0)	34.2 (23.5)**	33.5 (20.1)**	48.8 (29.2)	46.8 (23.7)	34.0 (23.7)**	33.7 (22.4)**
s. 25OH Vit D (ng/mL)	11.7 (5.7)	12.1 (6.0)	12.0 (6.1)	13.6 (6.7)**	11.1 (6.1)	13.4 (6.2)*	10.9 (5.3) ††	14.8 (6.3)**
Kidney function parameters								
GFR (mL/min/1.73 m ²)	74.65 (22.68)	77.87 (21.26)	73.01 (25.58)*	74.22 (18.81)*	74.61 (22.45)	74.83 (20.69)	73.22 (23.90)	75.08 (18.81)
Urinary sodium excretion (mEq/24h)	188 [151, 247]	202 [159, 227]	206 [156, 251] ††	145 [122, 206]**	201 [159, 246] †	179 [137, 214]**	196 [165, 244] ††	166 [130, 198]**
Urinary albumin excretion (mg/24h)	730 [416, 1227]	724 [441, 1233]	672 [403, 1290]†	519 [325, 1080]**	783 [468, 1295]†	626 [292, 1127]**	801 [441, 1365]††	481 [289, 837]**
24-h Urinary Alb/Cre Ratio (mg/g)	544 [272 to 771]	502 [288 to 762]	492 [294 to 874]†	388 [212 to 826]**	572 [307 to 908]††	408 [209 to 835]**	575 [330 to 919]††	359 [187 to 721]**
Urinary Ca Excretion (mg/24h)	70.2 [45 to 131]	85.6 [44 to 136]	111.6 [57 to 176]**	103.4 [55 to 177]*	75.8 [36 to 134]†	65.5 [38 to 115]**	137.9 [54 to 230]**	111.6 [60 to 206]**
Urinary P Excretion (mg/24h)	697.9 [448, 911]	707.5 [546, 876]	762.0 [565, 942]	671.7 [519, 844]	693.9 [497, 984]	715.7 [494, 857]	728.5 [498, 984]	608.0 [523, 845]
Albumin Fractional Clearance (x10 ⁵)	36.5 [18, 65]	27.6 [13, 55]	35.2 [15, 62]†	23.7 [8, 60]*	41.1 [25, 71]	28.2 [9, 56]	44.5 [18, 69]†	19.7 [11, 59]*
IgG Fractional Clearance (x10 ⁵)	6.9 [4, 19]	5.5 [3, 10]	7.9 [3, 16] †	4.8 [2, 17]*	10.0 [5, 18]	4.6 [2, 13]	9.3 [5, 16]	4.1 [2, 11]*

Data are mean (SD) or median [IQR]. * P < 0.05, ** P < 0.01 versus Baseline. † P < 0.05, †† P < 0.01 versus Low Sodium. Normal Ranges: Serum Calcium: 8.7-10.3 mg/dl, Serum Phosphate: 2.3-4.7 mg/dl; Urinary Calcium Excretion: 100-300 mg/24-hours; Urinary Phosphate Excretion: 300-1000 mg/24-hours.

Supplementary Table 2: Patients on pharmacological medications at baseline in the study group as a whole (Overall), and according to sodium diet and study treatment sequence

	Overall (n=115)	Low Sodium Diet (n=57)		High Sodium Diet (n=58)	
		Paricalcitol to Placebo (n=28)	Placebo to Paricalcitol (n=29)	Paricalcitol to Placebo (n=29)	Placebo to Paricalcitol (n=29)
Patients on Pharmacological Medications – n (%)					
- Antihypertensive agents					
Losartan	115 (100%)	28 (100%)	29 (100%)	29 (100%)	29 (100%)
Losartan monotherapy	19 (17%)	2 (7%)	6 (12%)	4 (14%)	7 (24%)
- Any BP lowering drug additional to Losartan:	96 (83%)	26 (93%)	23 (88%)	25 (86%)	22 (76%)
- Diuretics	72 (63%)	18 (64%)	21 (72%)	15 (52%)	18 (62%)
- Calcium-channel blockers	68 (59%)	17 (61%)	18 (57%)	15 (60%)	18 (67%)
- Beta blockers	44 (38%)	17 (61%)	7 (24%)	11 (38%)	9 (31%)
- Sympatholytic agents	18 (16%)	7 (25%)	5 (17%)	3 (10%)	3 (10%)
- Others	2 (2%)	0 (0%)	1 (3%)	0 (0%)	1 (3%)
- ACE inhibitors or ARBs other than Losartan	0	0	0	0	0
- Lipid-lowering agents:					
- Any	77 (67%)	23 (82%)	17 (59%)	21 (72%)	16 (55%)
- Statins	73 (63%)	22 (79%)	15 (52%)	20 (69%)	16 (55%)
- Omega-3 fatty acid	17 (15%)	3 (11%)	7 (24%)	5 (17%)	2 (7%)
- Fibrates	4 (3%)	1 (4%)	3 (10%)	0 (0%)	0 (0%)
- Ezetimibe	3 (3%)	1 (4%)	2 (7%)	1 (3%)	0 (0%)
- Hypoglycemic agents:					
- Any	109 (95%)	26 (93%)	29 (100%)	27 (93%)	27 (93%)
- Oral hypoglycemic agents alone	67 (58%)	15 (54%)	17 (59%)	18 (62%)	17 (59%)
- Insulin and/or other hypoglycemic agents	42 (36%)	11 (39%)	12 (41%)	9 (31%)	10 (35%)

Data are n (%).

Supplementary Table 3: Significance of the differences in changes in 24-hour albumin excretion rate between the two sodium diet groups at 1, 2 and 3 months after randomisation adjusted for pre-defined baseline covariates with or without baseline HbA_{1c} and changes in 24-hour Systolic or Diastolic Blood Pressure with or without concomitant changes in HbA_{1c} levels.

	Month	No adjustment for HbA _{1c} levels	Adjustment for baseline HbA _{1c} levels	Adjustment for follow-up changes in HbA _{1c} levels	Adjustment for baseline and follow up changes in HbA _{1c} levels
Adjustment for pre-defined baseline covariates	1	0.0277 *	0.0306 *	0.0354 *	0.0358 *
	2	0.0395 *	0.0384 *	0.0403 *	0.0353 *
	3	0.0094 **	0.0106 *	0.0097 **	0.0091 **
Adjustment for changes in 24-h Diastolic Blood Pressure	1	0.0173 *	0.0193 *	0.0207 *	0.0198 *
	2	0.0253 *	0.0251 *	0.0172 *	0.0154 *
	3	0.0105 *	0.0152 *	0.0047 **	0.0039 **
Adjustment for changes in 24-h Systolic Blood Pressure	1	0.0307 *	0.0330 *	0.0451 *	0.0422 *
	2	0.0508	0.0504	0.0383 *	0.0348 *
	3	0.0150 *	0.0152 *	0.0078 **	0.0067 **

*p < 0.05; **p < 0.01 (low sodium vs high sodium diet group).

Supplementary Table 4: Primary and secondary outcomes before and after paricalcitol or placebo treatment in the study group as a whole (independent of sodium intake)

	<i>Paricalcitol</i>		<i>Placebo</i>	
	<i>Pre</i>	<i>Post</i>	<i>Pre</i>	<i>Post</i>
24-hours BP recordings				
Systolic (mmHg)	145.1 (12.6)	144.1 (13.2)	145.0 (12.2)	143.4 (11.5)
Diastolic (mmHg)	79.5 (6.3)	79.2 (6.5)	79.2 (6.0)	78.7 (5.8)
Mean (mmHg)	101.0 (7.6)	100.2 (7.1)	100.8 (6.9)	99.7 (7.3)*
Laboratory parameters				
HbA _{1c} (mmol/mol)	58.4 (14.9)	58.0 (14.8)	56.9 (14.8)	56.5 (14.6)
Serum Glucose (mg/dL)	155.2 (53.7)	157.6 (61.8)	156.5 (54.1)	155.1 (58.3)
Total cholesterol (mg/dL)	172.5 (39.0)	171.1 (39.0)	169.4 (35.8)	172.1 (40.4)
HDL cholesterol (mg/dL)	43.8 (12.5)	43.4 (11.2)	42.8 (11.8)	43.3 (12.4)
Triglycerides (mg/dL)	164.9 (113.7)	171.7 (146.2)*	158.5 (92.6)	162.6 (119.0)
Calcium (mg/dL)	9.17 (0.34)	9.45 (0.43)**††	9.15 (0.32)	9.20 (0.29)*
Phosphorus (mg/dL)	3.40 (0.51)	3.79 (0.53)**††	3.33 (0.57)	3.43 (0.51)**
s. iPTH (pg/mL)	47.6 (23.5)	23.6 (16.8)** ††	47.8 (25.0)	44.2 (22.5)
s. 25OH Vit D (ng/mL)	11.7 (5.9)	13.1 (6.2)** †	12.4 (6.2)	12.5 (6.3)
Kidney function parameters				
GFR (mL/min/1.73 m ²)	75.03 (21.43)	73.84 (22.12)	75.97 (22.02)	73.47 (21.73)*
Urinary sodium excretion (mEq/24h)	189 [148, 231]	172 [136, 229]*	189 [152, 230]	184 [142, 228]
Urinary albumin excretion (mg/24h)	711 [413, 1225]	589 [338, 1077]**†	760 [415, 1227]	667 [364, 1243]
24-hour Urinary Albumin/Creatinine Ratio (mg/g)	489 [271, 853]	427 [227, 721]**	486 [255, 895]	461 [259, 887]
Urinary Calcium Excretion (mg/24h)	80.8 [43, 127]	166.96 [106, 246]**††	69.64 [41, 136]	68.64 [41, 126]
Urinary Phosphorus Excretion (mg/24h)	678.2 [528, 864]	730.9 [521, 907]*†	719.6 [521, 911]	654.6 [505, 872]
Fractional. albumin clearance (x10 ⁵)	34.86 [14.5, 64.7]	26.3 [12.2, 58.2]*	33.1 [13.4, 59.9]	28.0 [12.7, 66.8]
Fractional. IgG clearance (x10 ⁵)	7.0 [3.3, 17.1]	6.5 [2.7, 16.5]	7.3 [3.0, 15.8]	7.2 [3.2, 15.7]

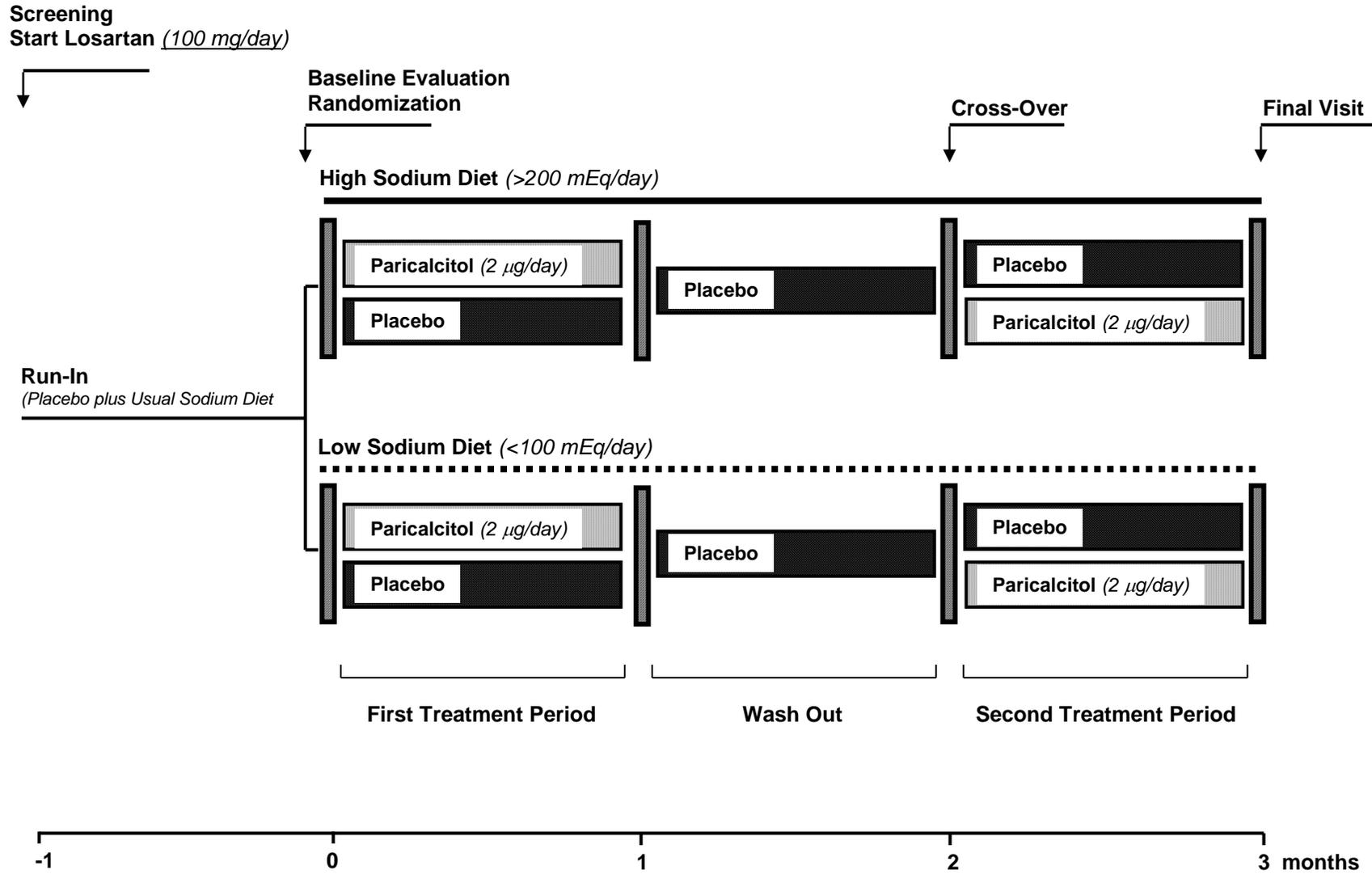
Data are mean (SD) or median [IQR]. GFR = glomerular filtration rate. * P < 0.05, ** P < 0.01 versus pre-paricalcitol or pre-placebo. † P < 0.05, †† P < 0.01 versus placebo. Normal Ranges: Serum Calcium: 8.7-10.3 mg/dl, Serum Phosphate: 2.3-4.7 mg/dl; Urinary Calcium Excretion: 100-300 mg/24-hours; Urinary Phosphate Excretion: 300-1000 mg/24-hours.

Supplementary Table 5: Pre-and post-treatment primary and secondary outcomes according to sodium arms and allocation to paricalcitol or placebo

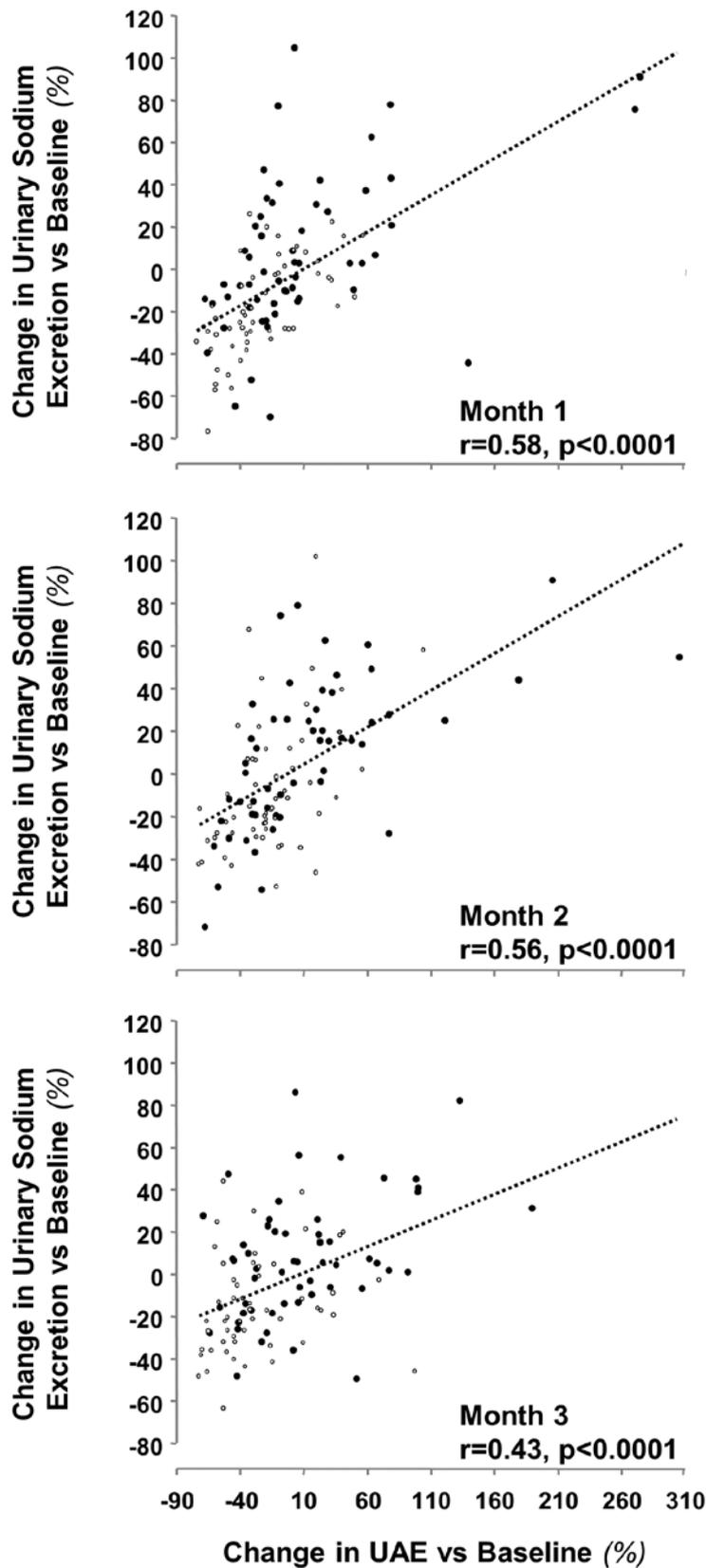
	High sodium diet				Low sodium diet			
	<i>Paricalcitol</i>		<i>Placebo</i>		<i>Paricalcitol</i>		<i>Placebo</i>	
	<i>Pre</i>	<i>Post</i>	<i>Pre</i>	<i>Post</i>	<i>Pre</i>	<i>Post</i>	<i>Pre</i>	<i>Post</i>
24-hours BP recordings								
Systolic (mmHg)	144.5 (12.1)	145.3 (12.0)	144.2 (12.0)	142.8 (11.2)	146.3 (12.1)	143.6 (13.9)	146.3 (12.4)	144.0 (12.1)
Diastolic (mmHg)	78.84 (6.2)	79.80 (6.9)	78.76 (5.9)	78.68 (6.2)	80.50 (6.2)	78.65 (6.1)*	79.70 (6.2)	78.46 (5.5)
Mean (mmHg)	100.39 (7.2)	101.30 (7.4)	100.24 (6.5)	99.32 (7.6)	102.09 (7.5)	99.31 (6.5)*	101.56 (7.3)	99.78 (7.0)
Laboratory parameters								
HbA _{1c} (mmol/mol)	58.74 (16.9)	58.83 (16.5)	56.81 (16.1)	57.83 (16.0)*	58.05 (12.8)	57.12 (13.0)*	57.08 (13.5)	55.21 (13.0)*
Serum Glucose (mg/dL)	162.3 (62.5)	165.1 (66.9)	163.8 (63.2)	169.2 (71.6)	148.0 (42.7)	150.0 (55.8)	149.1 (42.3)	141.0 (36.4)
Total cholesterol (mg/dL)	179.1 (38.2)	175.4 (37.9)	174.9 (35.7)	183.0 (40.3)**	165.9 (39.0)	166.7 (40.0)	163.8 (35.4)	161.1 (37.8)
HDL cholesterol (mg/dL)	46.33 (13.8)	45.52 (12.6)	44.95 (13.3)	46.34 (14.2)	41.47 (10.6)	41.26 (9.1)	40.72 (9.8)	40.47 (9.5)
Triglycerides (mg/dL)	158.1 (106.7)	153.6 (100.3)	163.5 (108.5)	169.0 (148.1)	171.8 (120.9)	190.2 (180.5)*	163.3 (73.8)	156.3 (81.0)
Calcium (mg/dL)	9.20 (0.34)	9.50 (0.48)**††	9.17 (0.30)	9.19 (0.29)	9.14 (0.34)	9.48 (0.38)**††	9.12 (0.34)	9.21 (0.29)**
Phosphorus (mg/dL)	3.46 (0.51)	3.85 (0.51)**††	3.44 (0.53)	3.50 (0.48)	3.34 (0.51)	3.73 (0.55)**†	3.21 (0.58)	3.37 (0.54)**
s. iPTH (pg/mL)	45.8 (25.1)	23.1 (15.9)**††	48.1 (27.1)	45.2 (27.8)	49.4 (21.9)	24.1 (17.7)**††	47.5 (22.9)	43.1 (20.2)*
s. 25OH Vit D (ng/mL)	11.4 (5.9)	11.7 (5.5)	11.4 (5.9)	11.2 (6.0)	12.1 (5.8)	14.5 (6.6)**††	13.4 (6.3)	13.8 (6.5)
Kidney function parameters								
GFR (mL/min/1.73 m ²)	73.62 (21.53)	73.52 (24.42)	75.82 (23.69)	72.07 (25.04)**	76.18 (21.66)	73.54 (19.86)	75.43 (19.64)	74.77 (17.77)
Urinary sodium excretion (mEq/24h)	200.6 [149, 233]	202.8 [159, 234]	183.9 [152, 256]	197.1 [165, 262]	187.3 [147, 230]	152.9 [129, 205]**	192.9 [152, 219]	167.0 [120, 198]**
Urinary albumin excretion (mg/24h)	750 [505, 1316]	651 [403, 1120]†	789 [408, 1287]	831 [487, 1365]	689 [356, 1225]	540 [289, 981]**	724 [415, 1198]	481 [315, 1084]**
24-hour Urinary Alb/Creat Ratio (mg/g)	588 [282, 853]	464 [286, 771]†	488 [254, 1128]	575 [343, 959]*	397 [242, 967]	386 [187, 717]**	453 [255, 762]	365 [209, 788]**
Urinary Calcium Excretion (mg/24h)	82.7 [41, 121]	157.6 [112, 261]**††	69.3 [42, 151]	74.5 [42, 142]	79.8 [44, 127]	169.4 [101, 233]**††	69.9 [38, 135]	65.3 [40, 117]
Urinary Phosph. Excretion (mg/24h)	685 [448, 999]	741 [506, 942]	724 [521, 914]	775 [506, 978]	678 [533, 846]	725 [550, 872]††	716 [513, 876]	604 [452, 810]**
Albumin Fractional. Clearance (x10 ⁵)	39.06 [18.6, 68.3]	35.65 [15.3, 57.5]	36.47 [22.5, 59.9]	37.82 [22.2, 69.3]	27.17 [11.9, 56.3]	20.38 [10.2, 62.1]*	28.36 [13.0, 53.6]	22.16 [8.7, 54.0]
IgG Fractional Clearance (x10 ⁵)	8.80 [4.2, 19.9]	7.98 [3.4, 16.6]†	8.15 [5.3, 17.6]	9.38 [5.3, 16.5]*	5.43 [2.6, 9.3]	5.06 [2.3, 13.7]	5.17 [2.8, 13.5]	4.58 [2.0, 12.0]

Data are mean (SD) or median [IQR]. GFR = glomerular filtration rate. * P < 0.05, ** P < 0.01 versus pre-paricalcitol or pre-placebo. † P < 0.05, †† P < 0.01 versus placebo. Normal Ranges: Serum Calcium: 8.7-10.3 mg/dl, Serum Phosphate: 2.3-4.7 mg/dl; Urinary Calcium Excretion: 100-300 mg/24-hours; Urinary Phosphate Excretion: 300-1000 mg/24-hours.

STUDY DESIGN

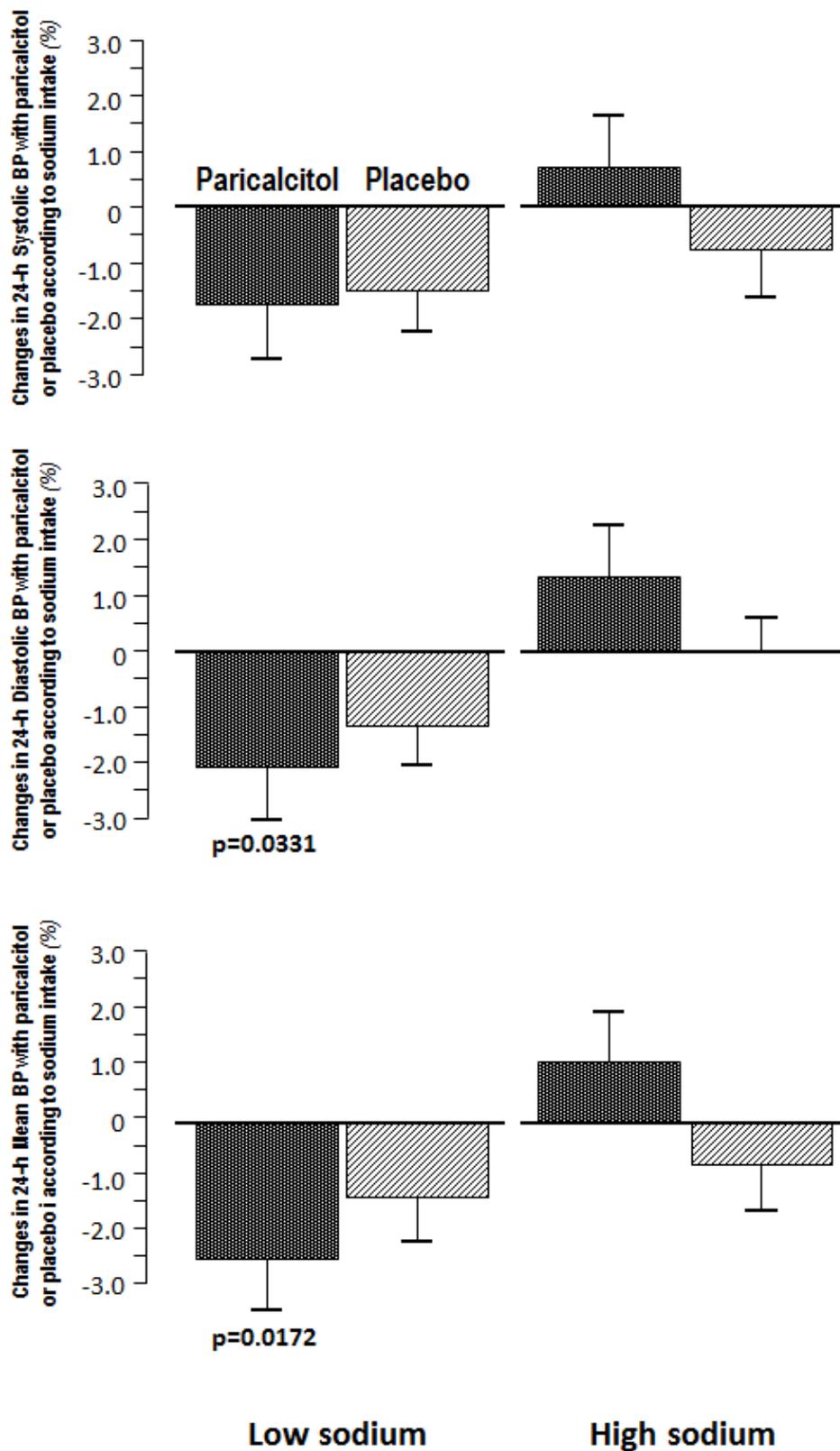


Supplementary Figure 1



Supplementary Figure 2

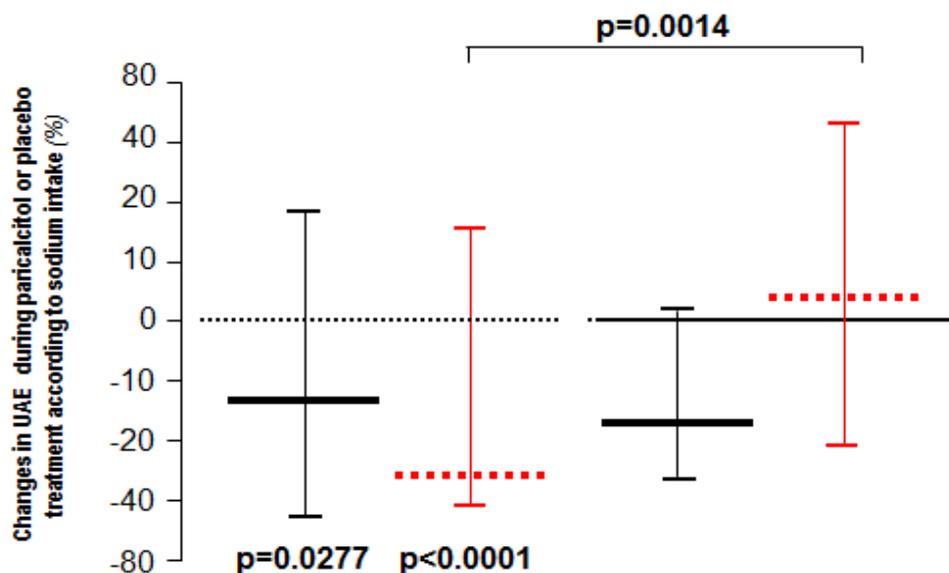
Correlations between percent changes in 24-hour urinary sodium and albumin excretion at month 1 (Top Panel), month 2 (Middle Panel) and month 3 (Bottom Panel) vs baseline in patients randomised to high (black circles) or low (white circles) sodium intake considered as a whole. All correlations were highly significant. Abbreviations: UAE = urinary albumin excretion.



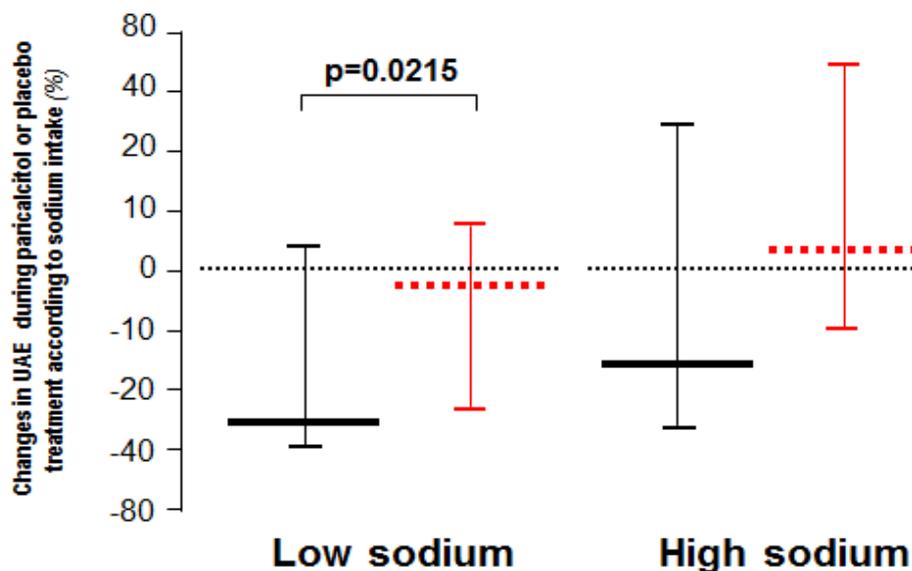
Supplementary Figure 3

Mean (SEM) percent changes in 24-hour systolic (Top Panel), diastolic (Middle Panel) and mean (Bottom Panel) BP during 1-month paricalcitol (black histograms) or placebo (dashed histograms) treatment in the low (Left Panel) and high (Right Panel) sodium diet groups considered separately. Abbreviations: BP = blood pressure.

First Treatment Period



Second Treatment Period



Supplementary Figure 4

Median (IQR) percent changes in 24-hour urinary albumin excretion in the first study period immediately after randomisation (Top Panel) and in the second study period immediately after the cross-over (Bottom Panel) during 1-month paricalcitol (continuous bars) or placebo (dotted bars) treatment in the low (Left Panel) and high (Right Panel) sodium diet groups considered separately. Abbreviations: UAE = urinary albumin excretion.

PROCEED Study Organization

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