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A Pilot Randomized Trial of Cholecalciferol Supplementation in CKD

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Objectives : Vitamin D deficiency is common in CKD and associated with CVD and bone mineral metabolism. Despite short term favourable effects, long term impact of cholecalciferol supplementation is unknown. We aimed to test the effects of cholecalciferol supplementation on CVD outcomes, progression of CKD and markers of bone-mineral metabolism and inflammation in patients with pre-dialysis CKD by way of a double blind, placebo-controlled, randomized clinical trial.
Methods : The study was a single center, prospective, randomized (1:1), placebo controlled, double blind clinical trial. Inclusion criteria were ages between 18-75 years, eGFR 10-45 ml/min/1.73m^2, serum 25-hydroxy vitamin D [25(OH)D] levels 20-50 ng/ml and clinically stable course for last 3 months. After 2 weeks run-in phase, participants received either cholecalciferol 60000 IU once/2 weeks or matching placebo. Follow up visits were scheduled at every 3 months till 36 months after enrolment. All clinical and demographic characters and biomarkers were analyzed at baseline and annual follow up.
Results : 692 patients were screened, out of which 126 were enrolled (Figure 1). However, 37 participants dropped out before randomization on account of COVID-19 related lockdowns or other reasons. The pilot phase was stopped in April 2023. Follow up course of 89 participants were available till that time (Figure 1). Both the groups were similar with respect to MACE events, need of RRT and all-cause mortality. Over one year, serum 25 (OH) vitamin D increased in the cholecalciferol group [Mean diff between groups: 31.89, 95% CI: 20.46 to 43.32, P<0.001 (Table 1)]. Serum calcium increased whereas CRP and bone specific alkaline phosphatase (BAP) levels decreased in the cholecalciferol group.
Conclusions : Cholecalciferol supplementation in vitamin D non-deficient patients with CKD favourably affected markers of inflammation and bone mineral metabolism. A larger trial with sufficient duration of follow up is required to ascertain its clinical impact.

Figures Consort diagram calmckd 29 Dec 23 VK Jan 3, Jan 9 2024.jpg

Figure 1: Study enrolment and follow up

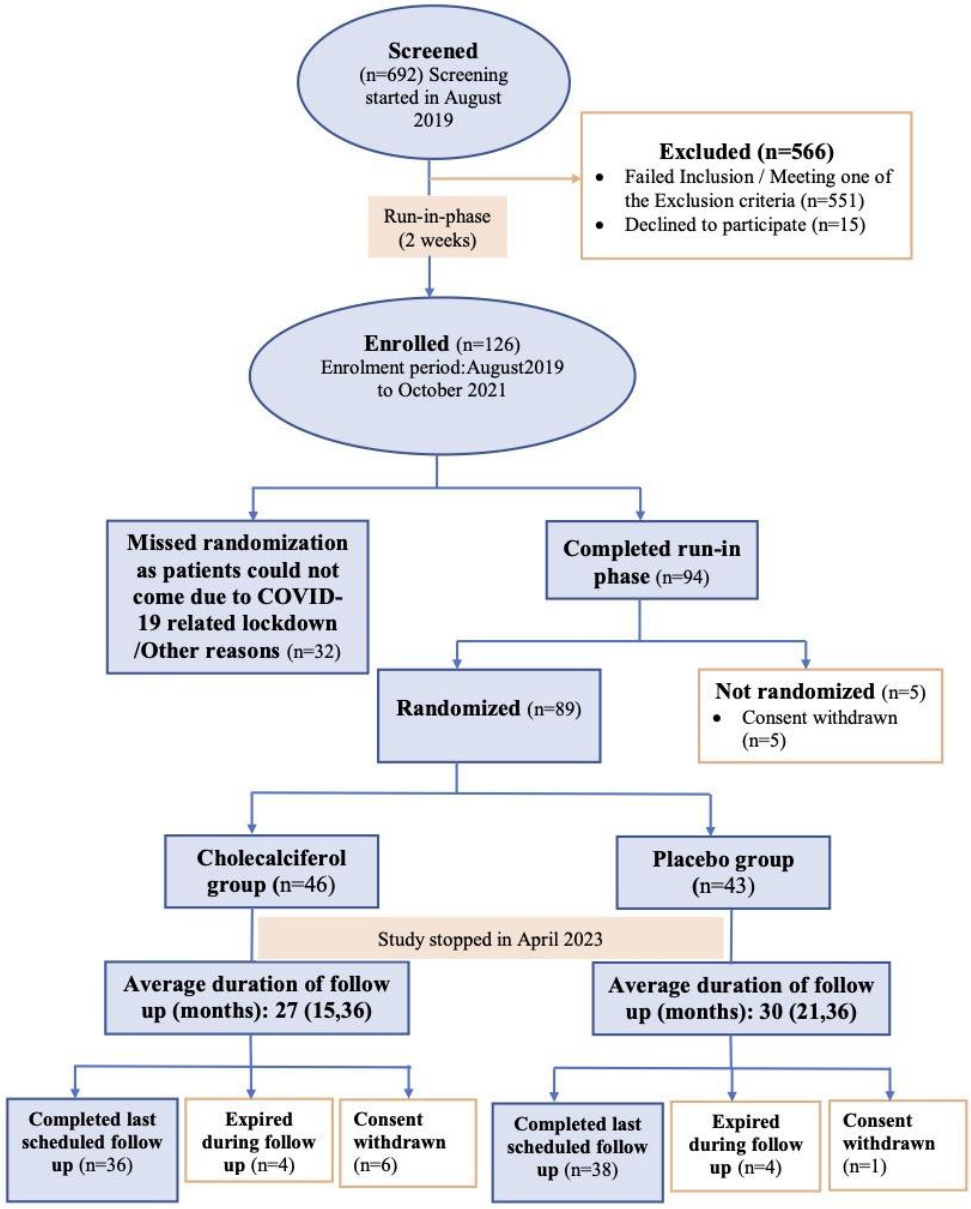

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Table 1: Within group and between group differences in biochemical and biomarker measurements at 12 months in the study population who completed at least one year follow up

Parameters	Cholecalciferol Mean difference (95%CI)	P value	Placebo Mean difference (95% CI)	P value	Between group difference	P value
Serum 25(OH)D (ng/mL)	31.15 (21.37 to 40.92)	<0.001	-0.75 (-7.43 to 5.94)	0.510	31.89 (20.46 to 43.32)	<0.001
Serum iPTH (pg/mL)	35.51 (-24.19 to 95.94)	0.329	58.39 (-17.92 to 134.69)	0.081	-22.87 (-119.56 to 73.81)	0.660
Hemoglobin (g/dL)	-0.21 (-0.89 to 0.48)	0.642	-0.37 (-0.75 to 0.020)	0.07	0.160 (-0.61 to 0.93)	0.442
Serum Cr (mg/dL)	0.46 (0.12 to 0.81)	0.029	0.44 (0.071 to 0.81)	0.010	0.022 (-0.47 to 0.52)	0.871
eGFR (CKD-EPIcr)	-1.72 (-3.80 to 0.37)	0.07	-2.54 (-4.71 to -0.38)	0.021	0.82 (-2.13 to 3.78)	0.848
Serum calcium (mg/dL)	0.72 (-0.14 to 0.29)	0.817	-0.49 (-0.82 to -0.15)	0.001	0.558 (0.17 to 0.95)	0.024
Serum inorganic phosphorous (mg/dL)	0.80 (0.006 to 1.59)	0.010	0.29 (-0.088 to 0.658)	0.238	0.517 (-0.35 to 1.39)	0.270
Serum alkaline phosphatase (U/L)	8.26 (-12.11 to 28.62)	0.648	15.28 (1.19 to 29.37)	0.023	-7.02 (-31.56 to 17.52)	0.197
UPCR (mg/g)	215.11 (-878.61 to 1308.83	0.040	-49.12 (-523.19 to 425.67)	0.264	264.23 (-950.39 to 1478.85)	0.664
Serum IL-6 (pg/mL)	-0.244 (-22.75 to 22.26)	0.694	-4.56 (-14.69 to 5.57)	0.081	4.315 (-19.08 to 27.72)	0.221
Serum intact FGF-23 (pg/mL)	101.74 (21.72 to 181.76)	0.001	82.08 (15.74 to 148.43)	0.015	19.66 (-81.75 to 121.06)	0.335
Serum CRP (ng/mL)	-0.105 (-1.65 to 1.44)	0.909	1.86 (0.51 to 3.23)	0.004	-1.97 (-3.99 to 0.04)	0.042
Serum CTX (ng/mL)	-0.395 (-0.68 to -0.112)	0.020	-0.185 (-0.53 to 0.16)	0.288	-0.215 (-0.655 to 0.23)	0.452
Serum BAP (U/L)	-4.61 (-9.90 to 0.68)	0.074	0.471 (-5.25 to 6.20)	0.085	-5.08 (-12.80 to 2.64)	0.019