Impact of Cinacalcet on cardiovascular outcomes in CKD patients with secondary hyperparathyroidism; The Stockholm CREAtinine Measurements (SCREAM) project

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Background: Secondary hyperparathyroidism is linked to worse outcomes in both CKD non dialysis and dialysis patients. Cinacalcet effectively lowers parathyroid hormone (PTH) levels.

Previous observational studies investigating associations between cinacalcet and outcomes are inconclusive, and biased by time-dependent confounding and patient selection.

Here we studied the impact of cinacalcet treatment on cardiovascular risk in the complete referred CKD, transplantation and dialysis population with secondary hyperparathyroidism in the region of Stockholm using marginal structural models.

Methods: Epidemiological analysis in SCREAM, a complete healthcare utilization database of Stockholm region during 2006-2011.

Inclusion criteria: Referred CKD patients stage G3+ (nondialysis CKD, dialysis and transplanted) with PTH 2*reference value (>130 ng/L) = index date.

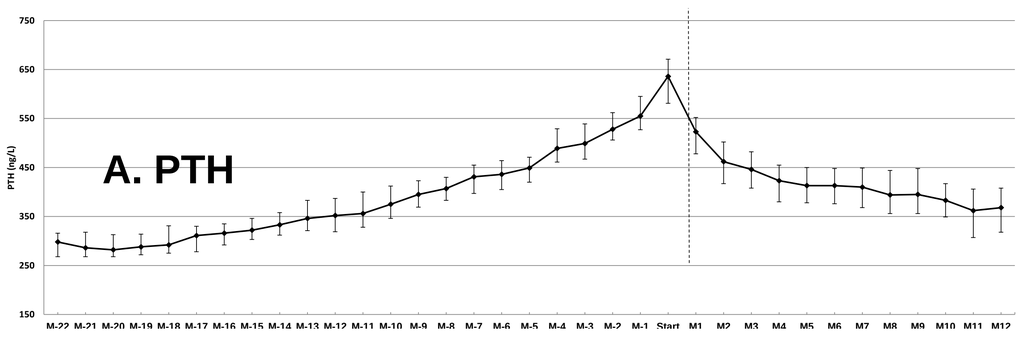
Confounders used to estimate probability of treatment weights and censoring weights:

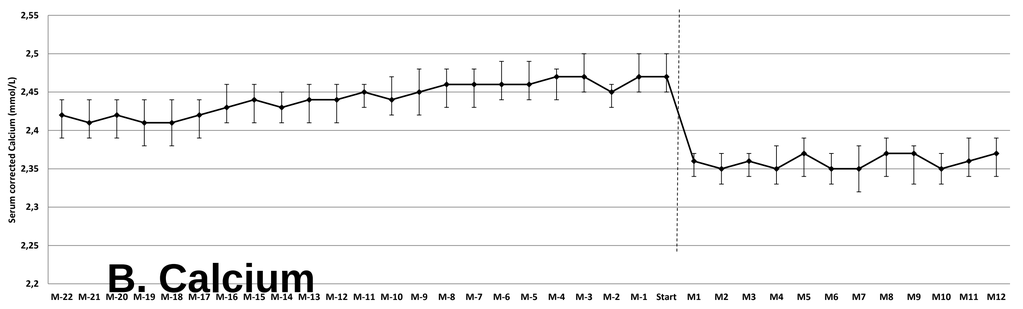
- Dialysis and transplantation transitions
- Comorbidity at baseline and during follow-up
- All relevant medications since index date (ESA, phosphate binders, vitamin D, predisolone, ACEi/ARB, betablockers)
- All laboratory values since index date (PTH, Calcium, Phosphate, Hemoglobin, Albumin, Creatinine, eGFR, CRP, ACR)
- Time of follow-up and trends of confounders over time

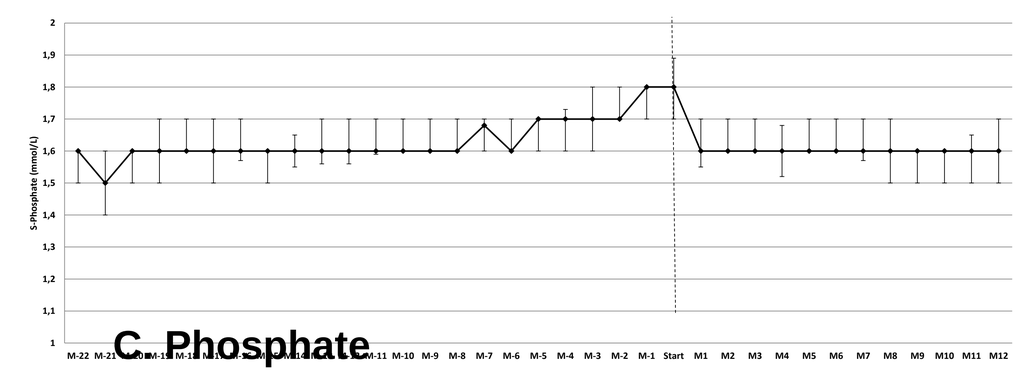
Primary outcome: The combination of cardiovascular death or a new cardiovascular event (hospitalization with angina, myocardial infarction, stroke, heart failure or peripheral arterial disease).

Variable, if missing data [n]	Index date	At Cinacalcet initiation (n=435)
Age, median years	66.6 (55.1-76.2)	60.8 (50-70)
Men	2,305 (64.5)	252 (57.9)
Cardiovascular disease/new CVD	1,497 (41.9)	142 (32.6)
Diabetes mellitus	768 (21.5)	86 (19.8)
Charlson comorbidity index, mean	3.92 (2.1)	3.68 (1.9)
Parathyroid hormone, median	185 (150 – 269)	636 (436-860)
Hemoglobin [3481]	119.7 (16.9)	119.5 (15.1)
P-Albumin, median [3477]	35 (32 – 38)	34.0 (4.3)
P-Calcium [3495]	2.26 (0 .18)	2.45 (2.28-2.59)
P-phosphate, median[3473]	1.4 (1.1 – 1.6)	1.8 (1.4-2.2)
Macroalbuminuria (ACR>30mg/mmol)	1,099 (50.8)	178 (70.9)
eGFR, median [3536]	18.4 (9.0 – 27.0)	n.a
ACEi or ARB	2,532 (70.9)	283 (65.1)
Vitamin D (active)	1,656 (46.4)	316 (72.6)
Calcium supplement	1,147 (32.1)	196 (45.1)
Other phosphate binder	514 (14.4)	316 (72.6)
Dialysis	646 (18.1)	272 (62.5)
Renal transplantation	419 (11.7)	54 (12.4)

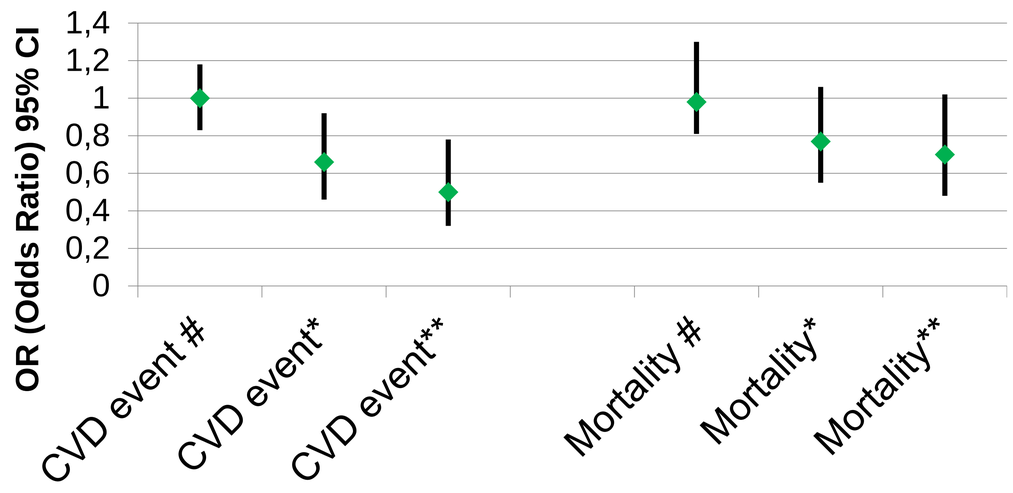
Development of parathyroid hormone (A), corrected calcium (B) and phosphate (C) before and after Cinacalcet initiation







Risk of cardiovascular event/mortality associated with cinacalcet treatment: a marginal structural model approach



Unadjusted
*Fully weighted with truncation of weights at 1,99th percentile
**Fully weigthed without truncation of treatment weights

Conclusion:

Treatment with cinacalcet was associated with lower risk of cardiovascular events.

In general, those treated with cinacalcet had progressive disturbances in calcium, phosphate and PTH before treatment was started, which were improved after cinacalcet initiation.

54 ERA
349--SP
CKD - MBD
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