

Eneboparatide e Calciolitici

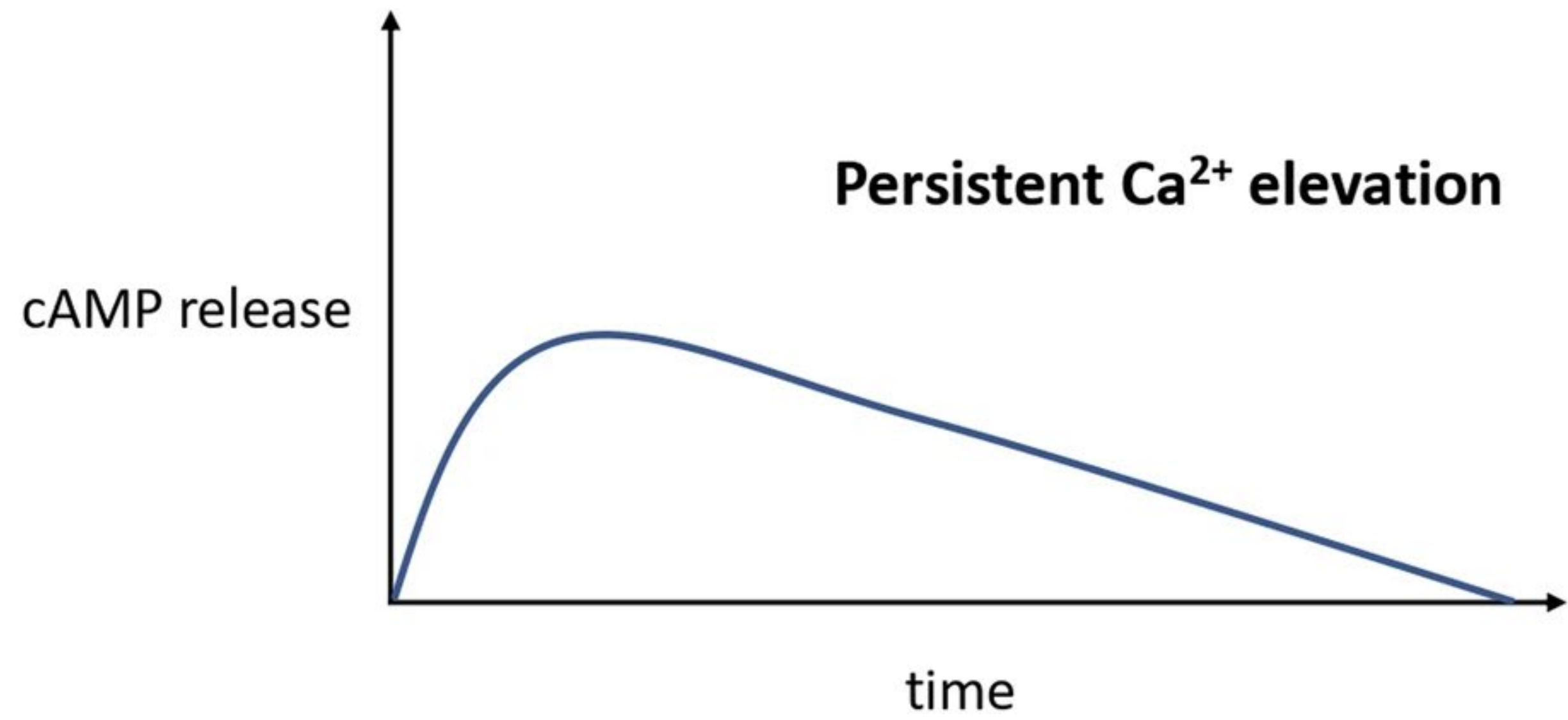
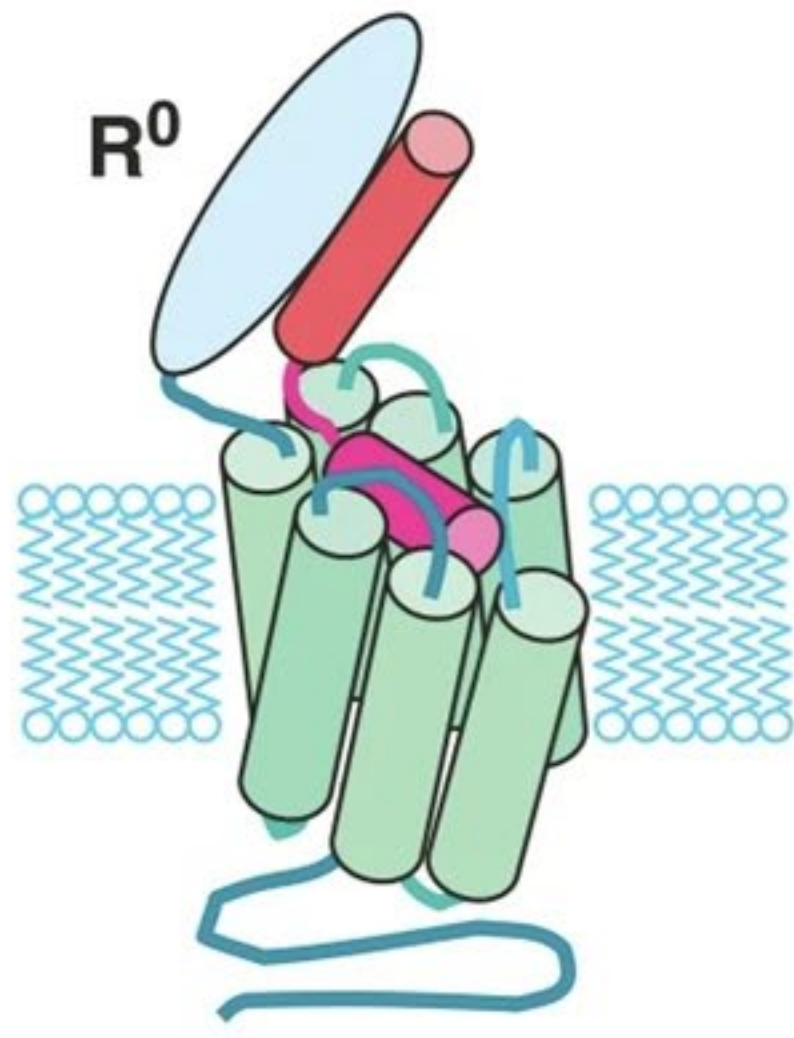
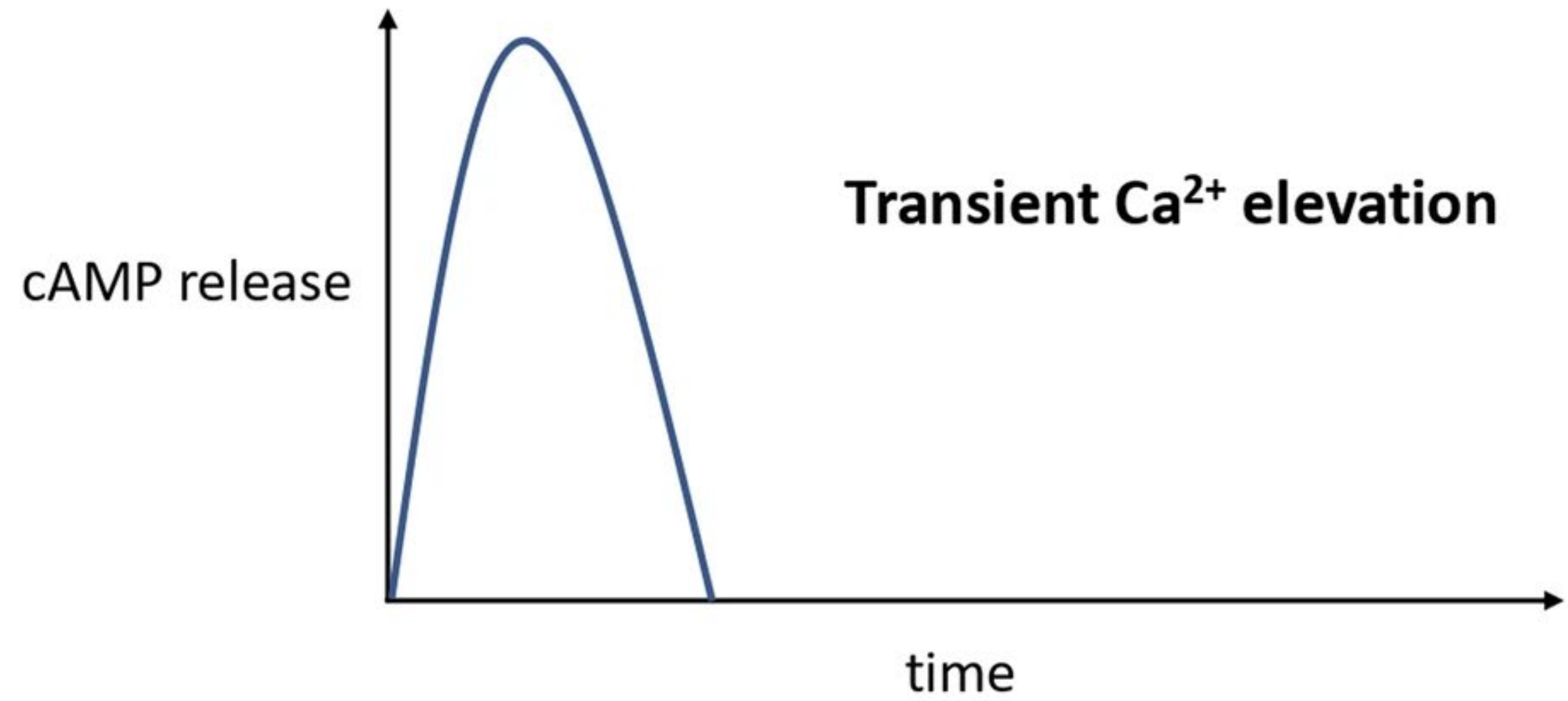
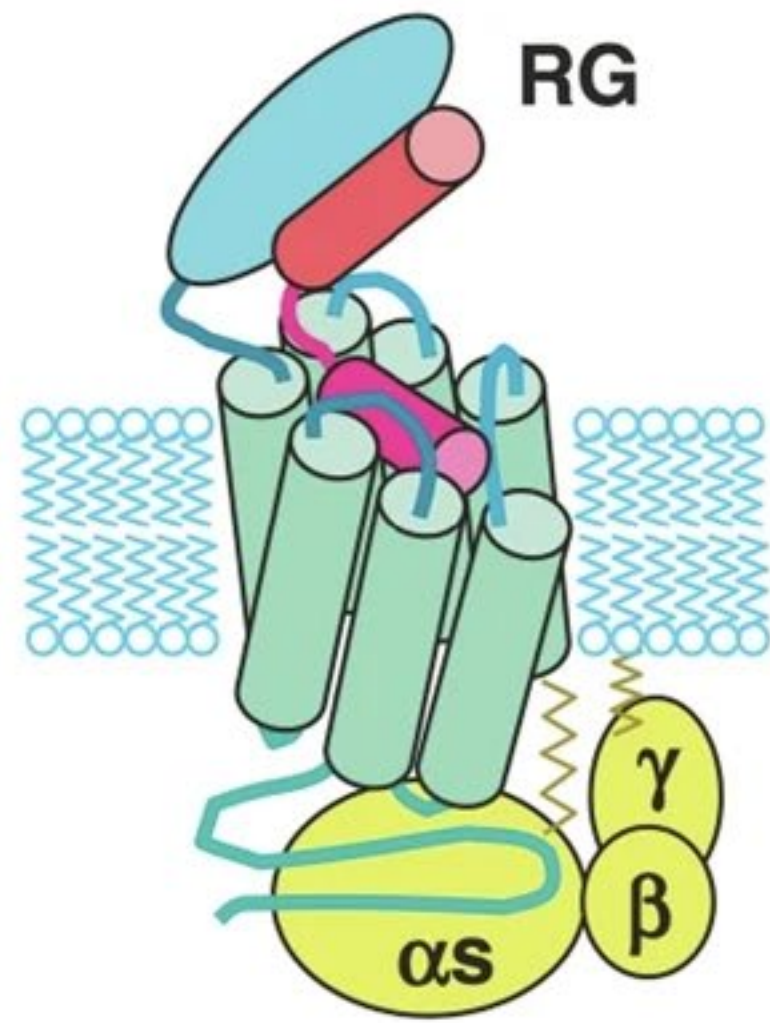
Stefano Mora

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Department of Pediatrics

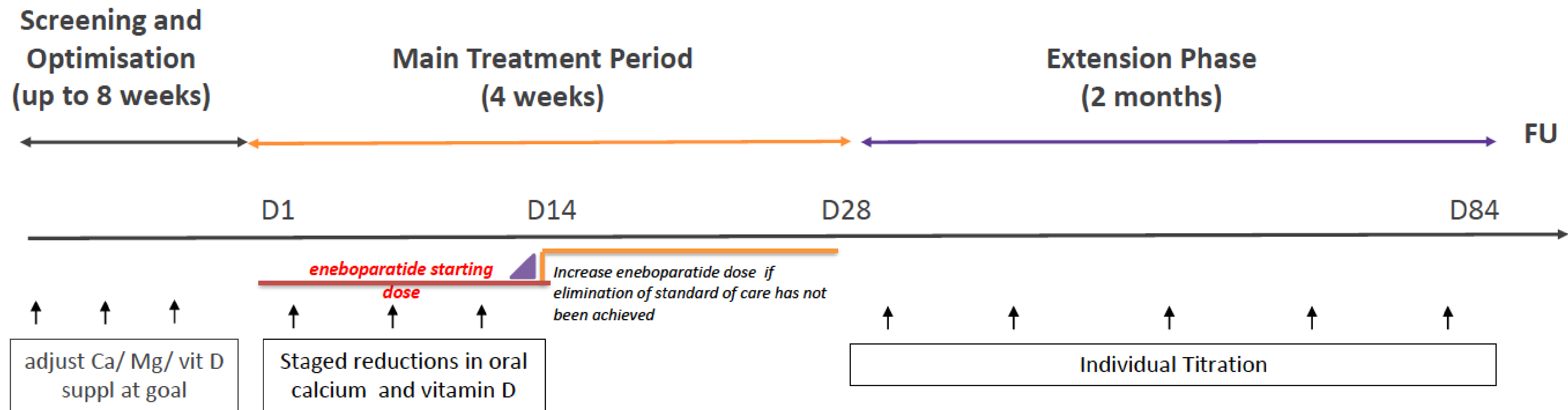
IRCCS Ospedale San Raffaele

Eneboparatide



NCT05239221

- Phase 2a clinical trial
- 3 locations
- Males and Females, 18-75 years of age
- Patients with CHP for ≥ 12 months at the time of screening
- Eneboparatide: administered once daily by subcutaneous injection



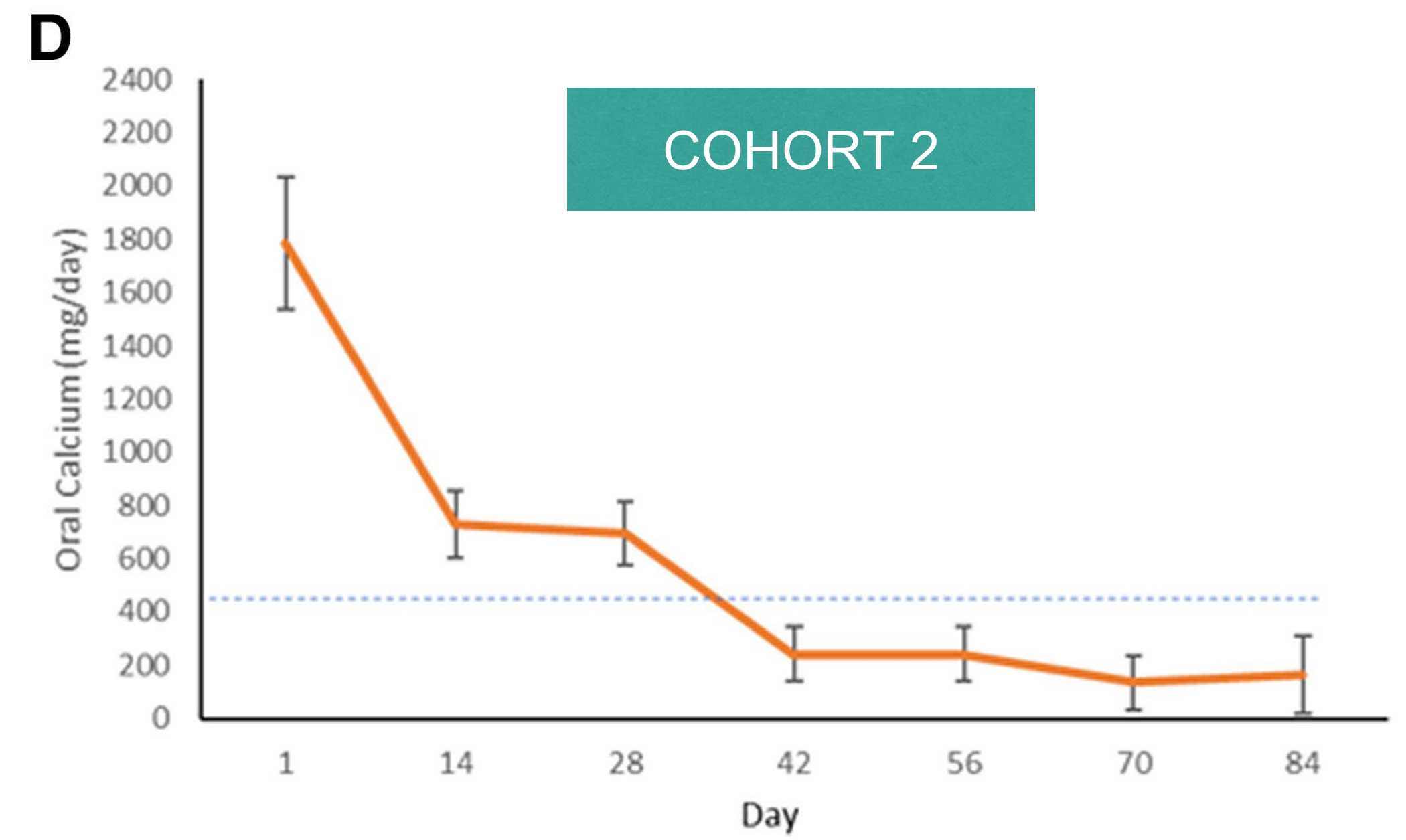
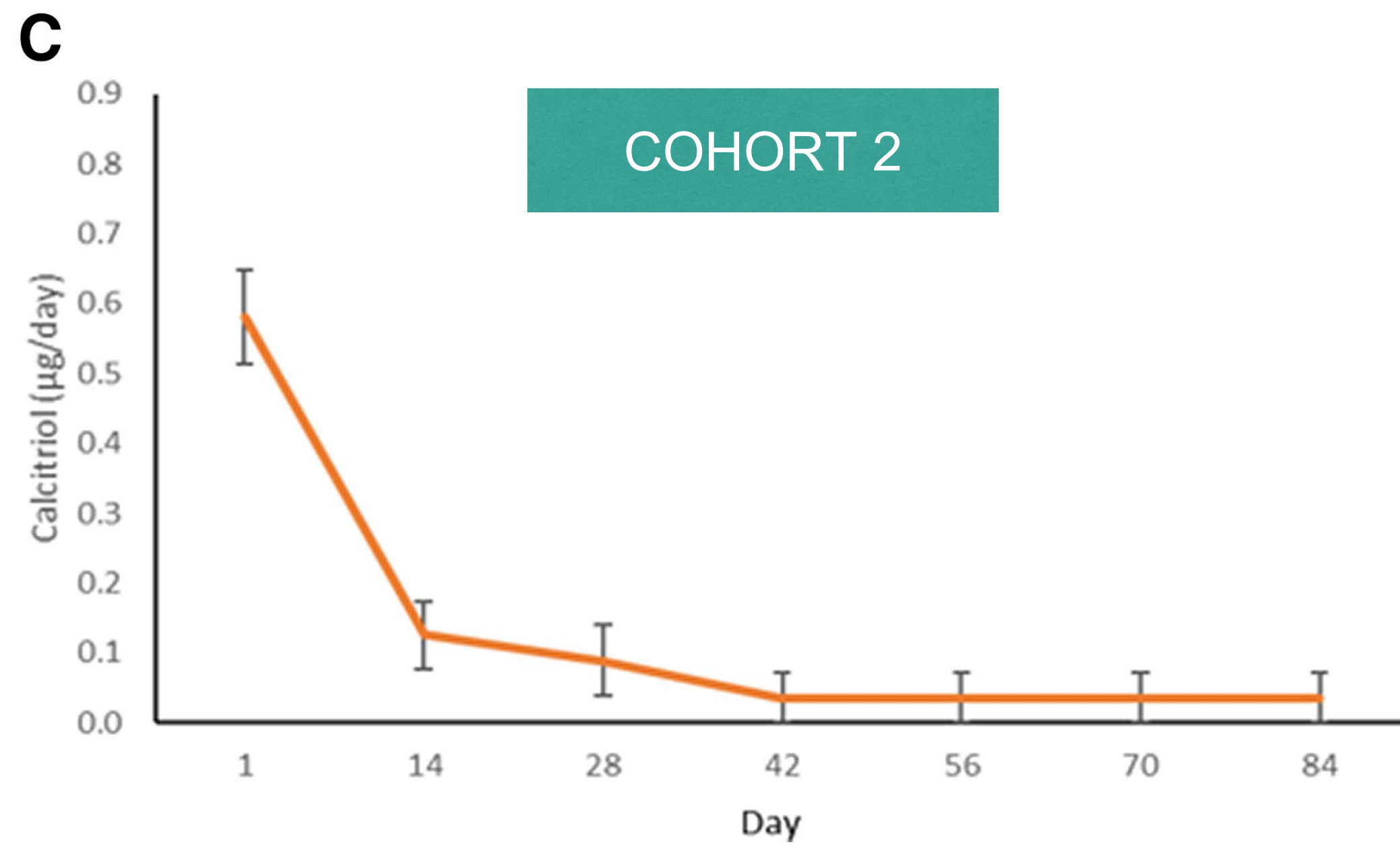
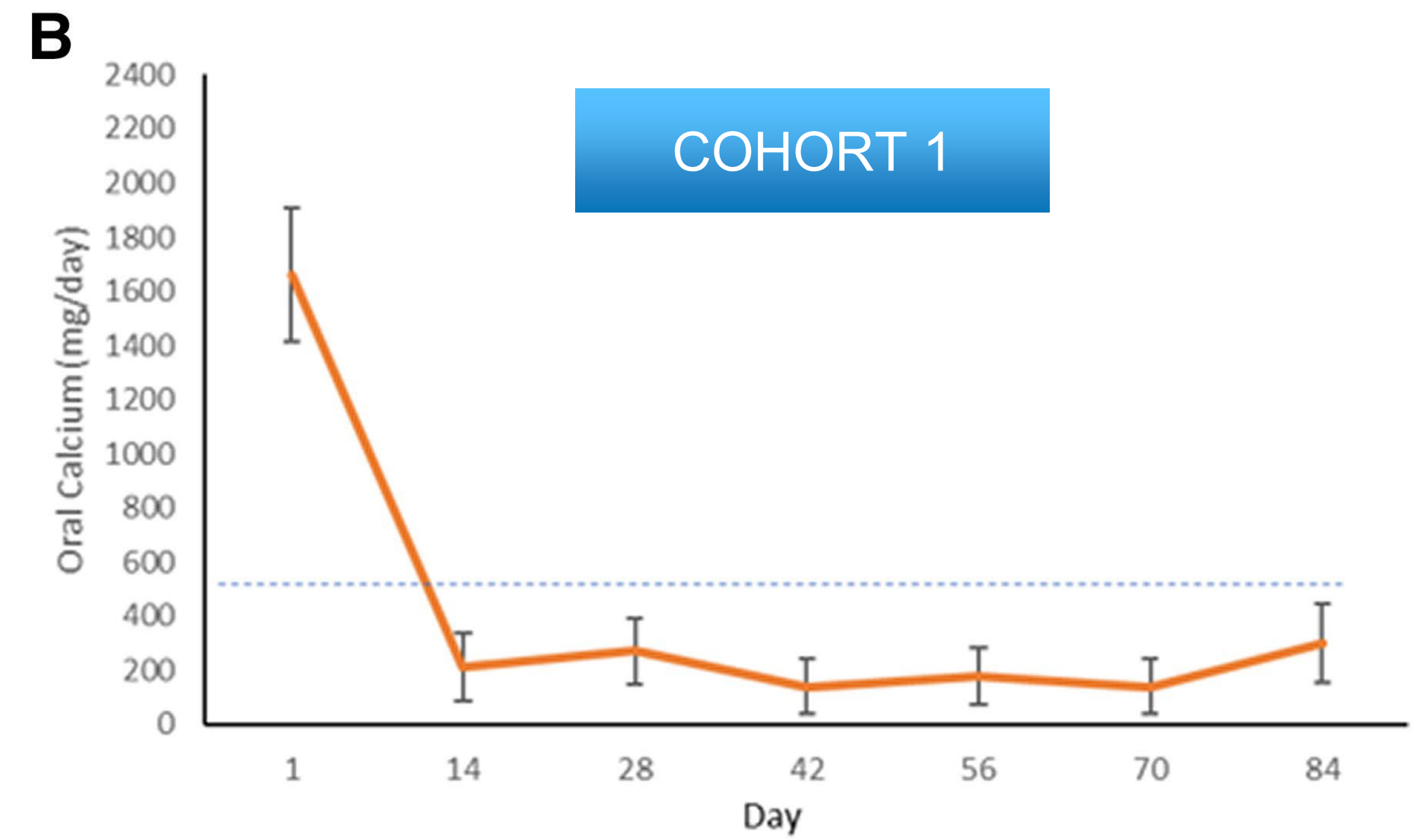
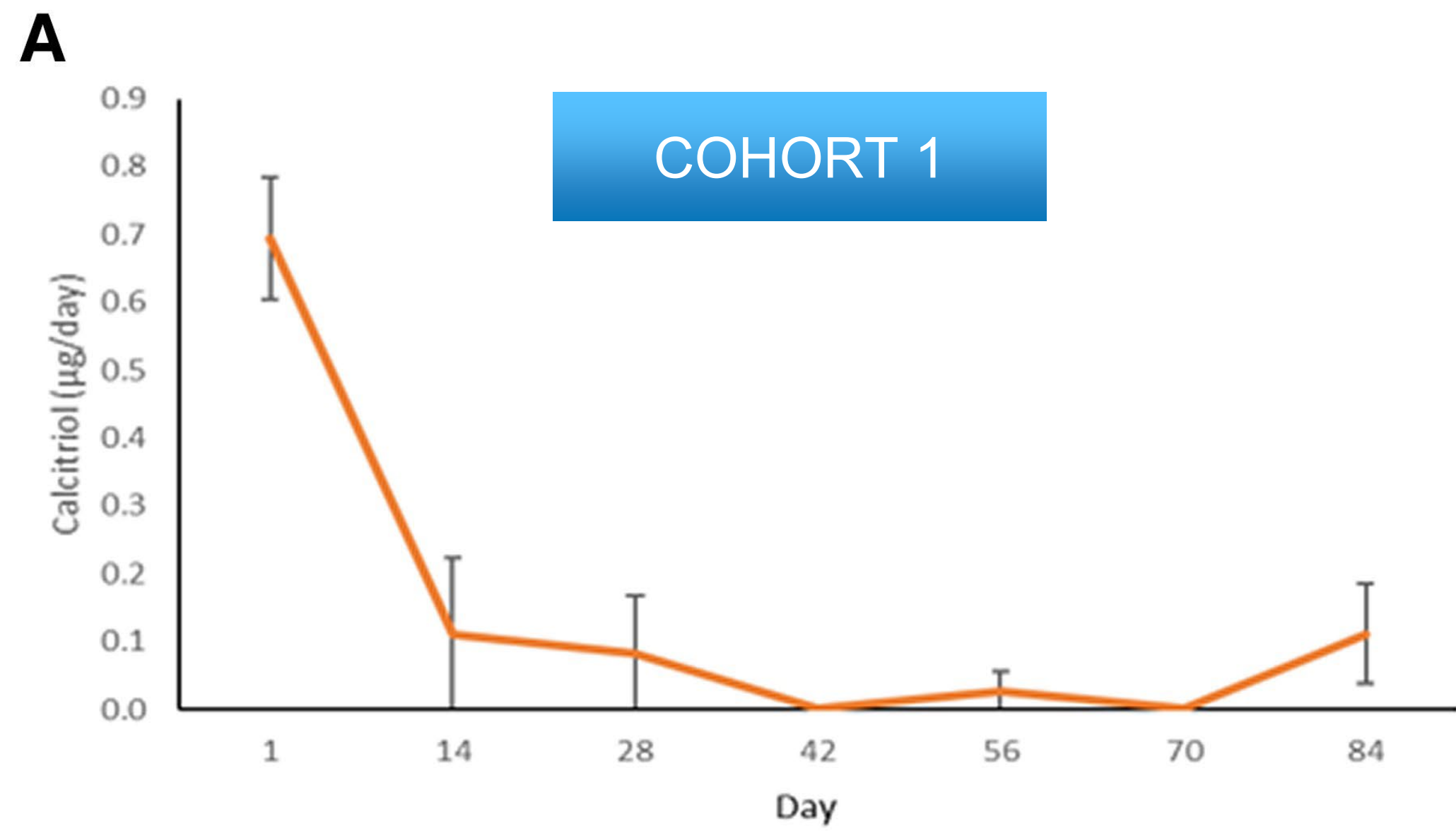
Target range for serum calcium defined as 7.8 to 9 mg/dL (1.95-2.25 mmol/L)

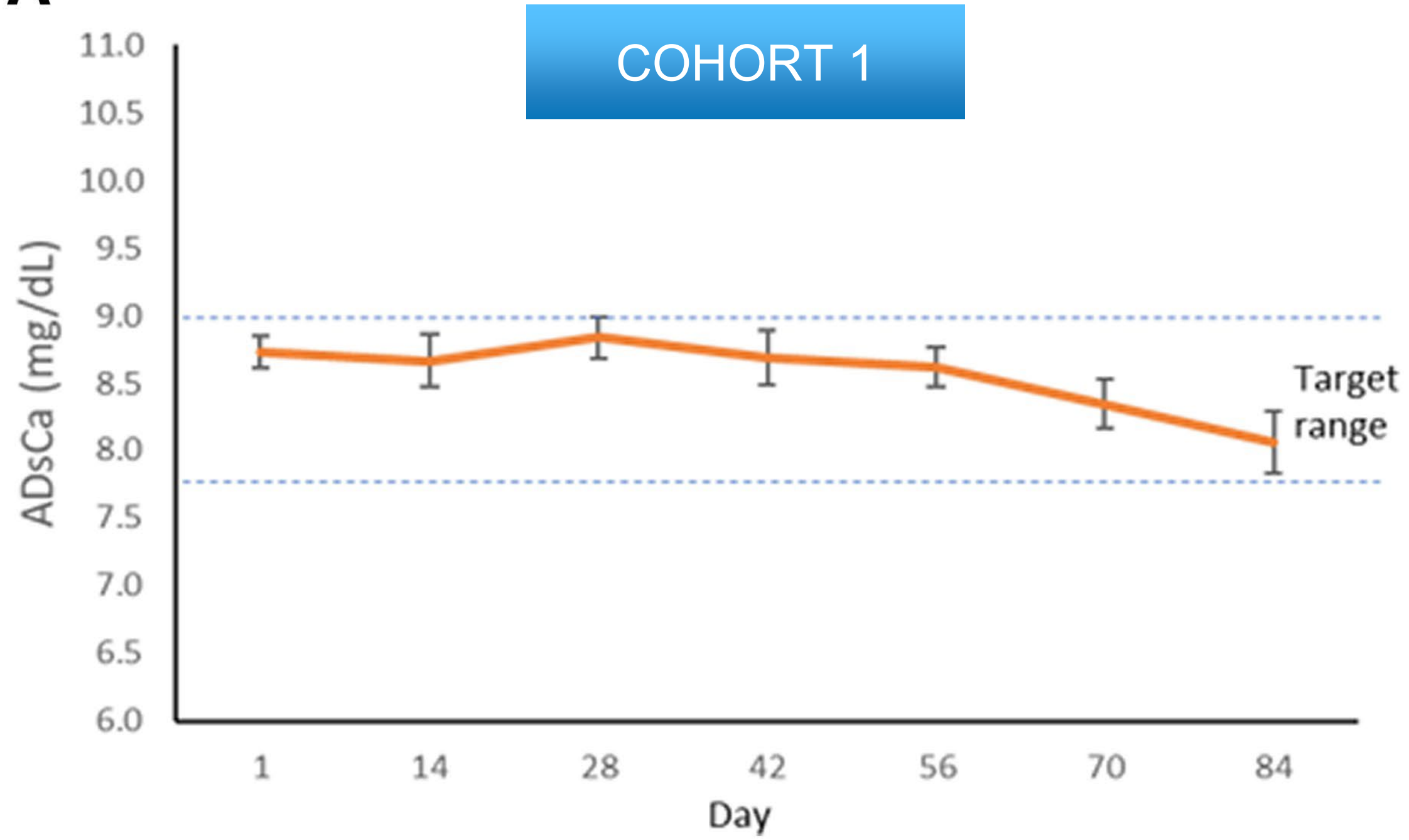
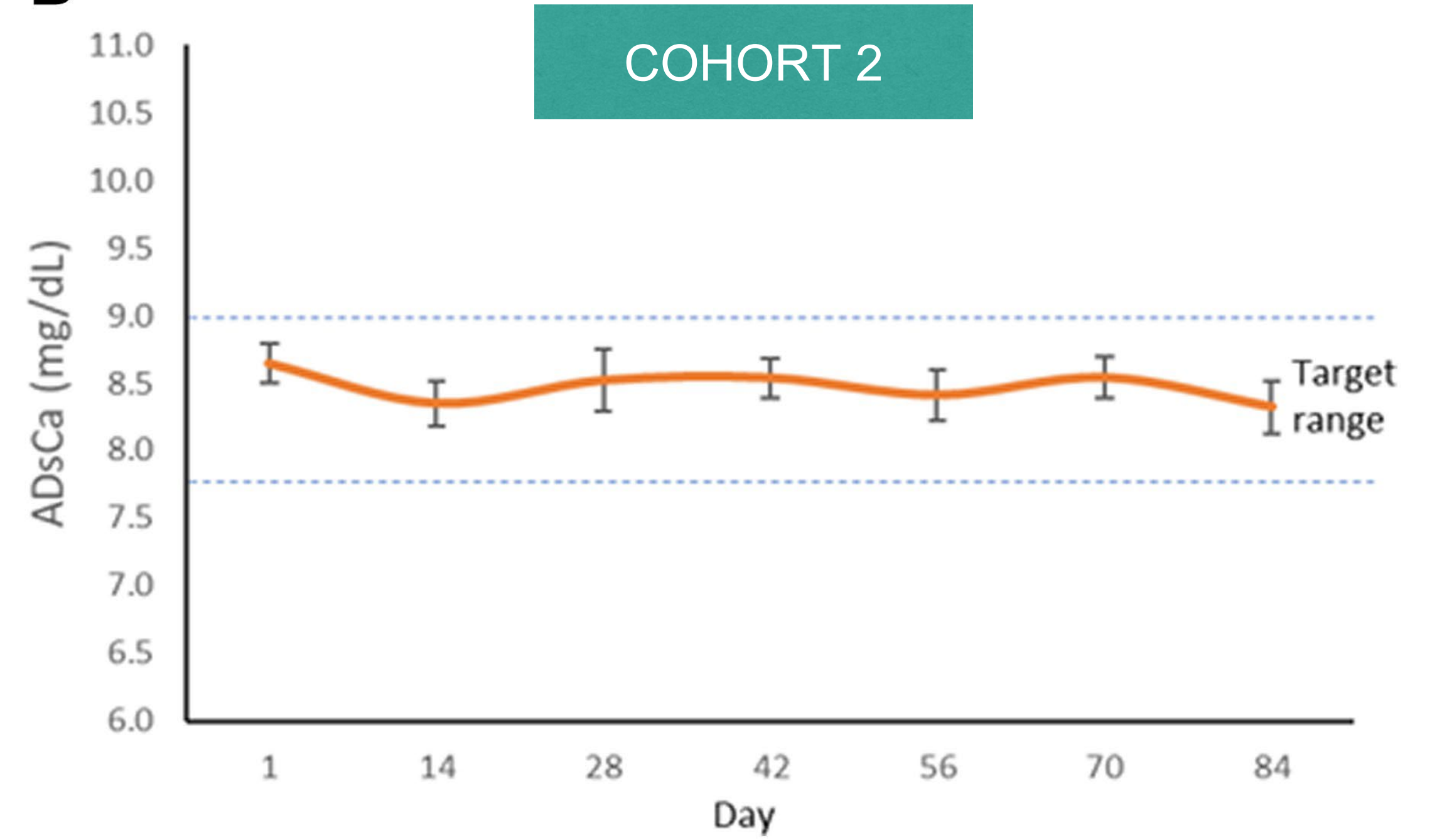
COHORT 1

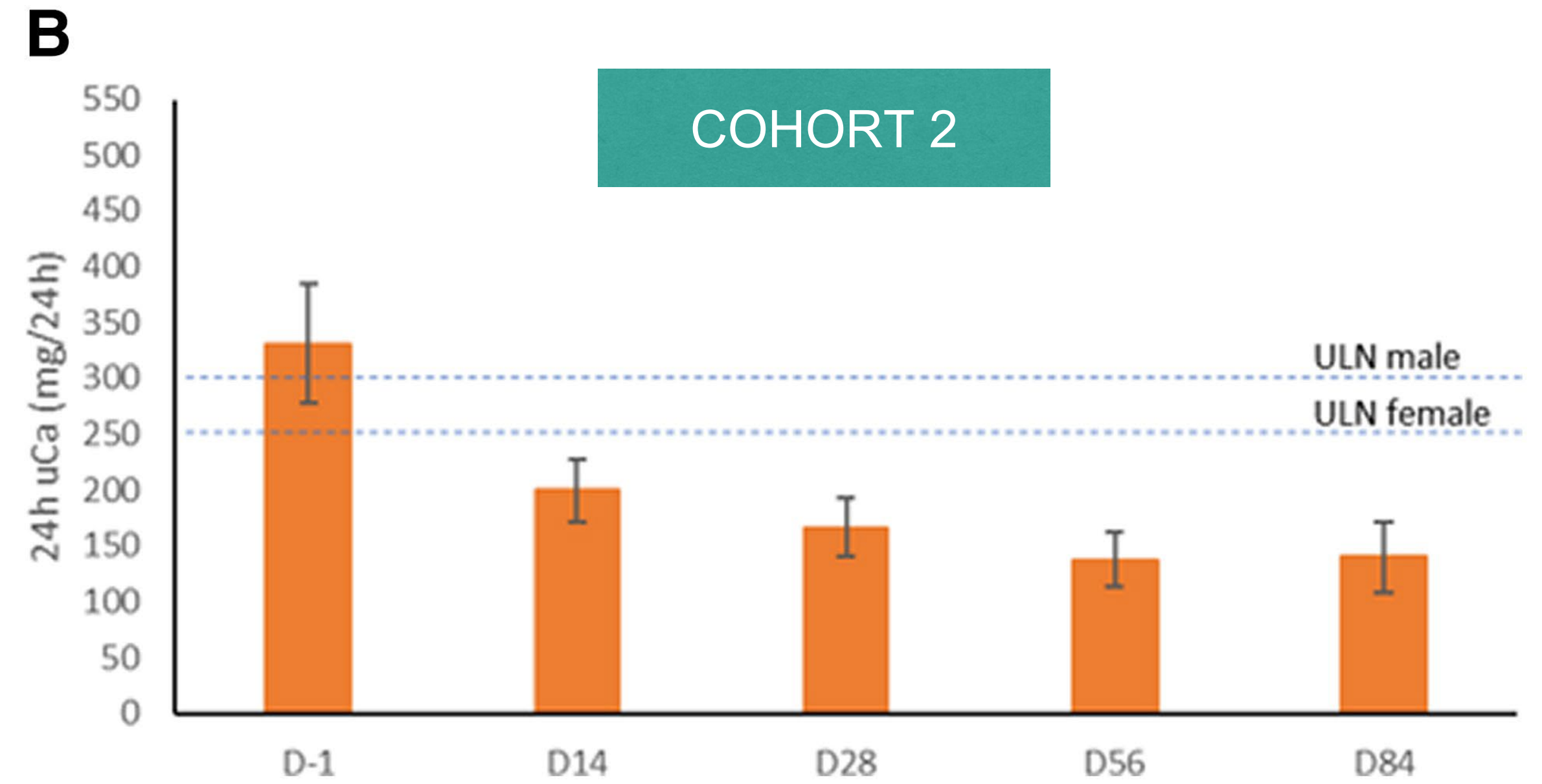
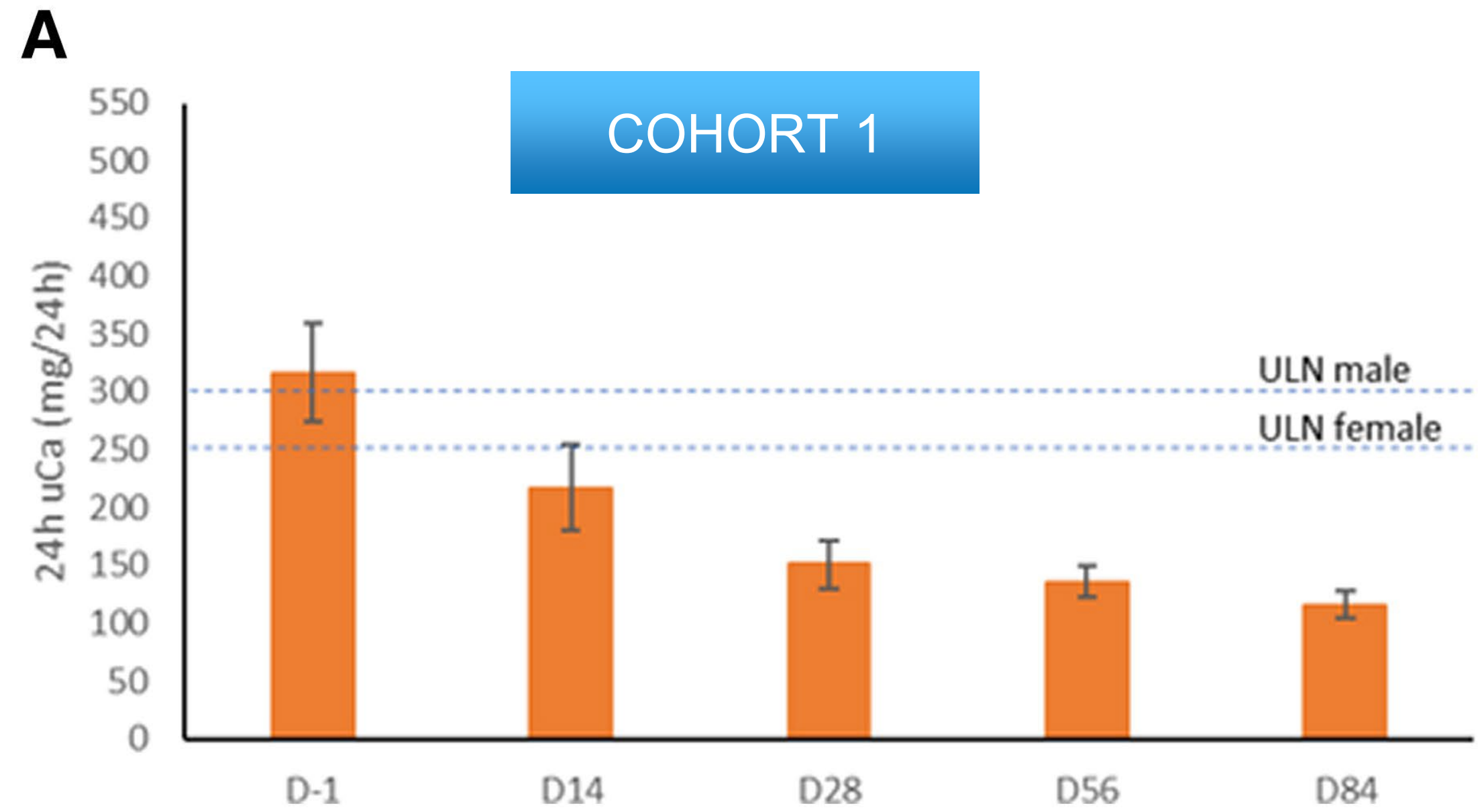
20 µg/day sc
 Staged reduction:
 50% at day 5
 75% at day 8
 100% at day 11

COHORT 2

10 µg/day sc
 Staged reduction:
 50% at day 3
 75% at day 5
 100% at day 8

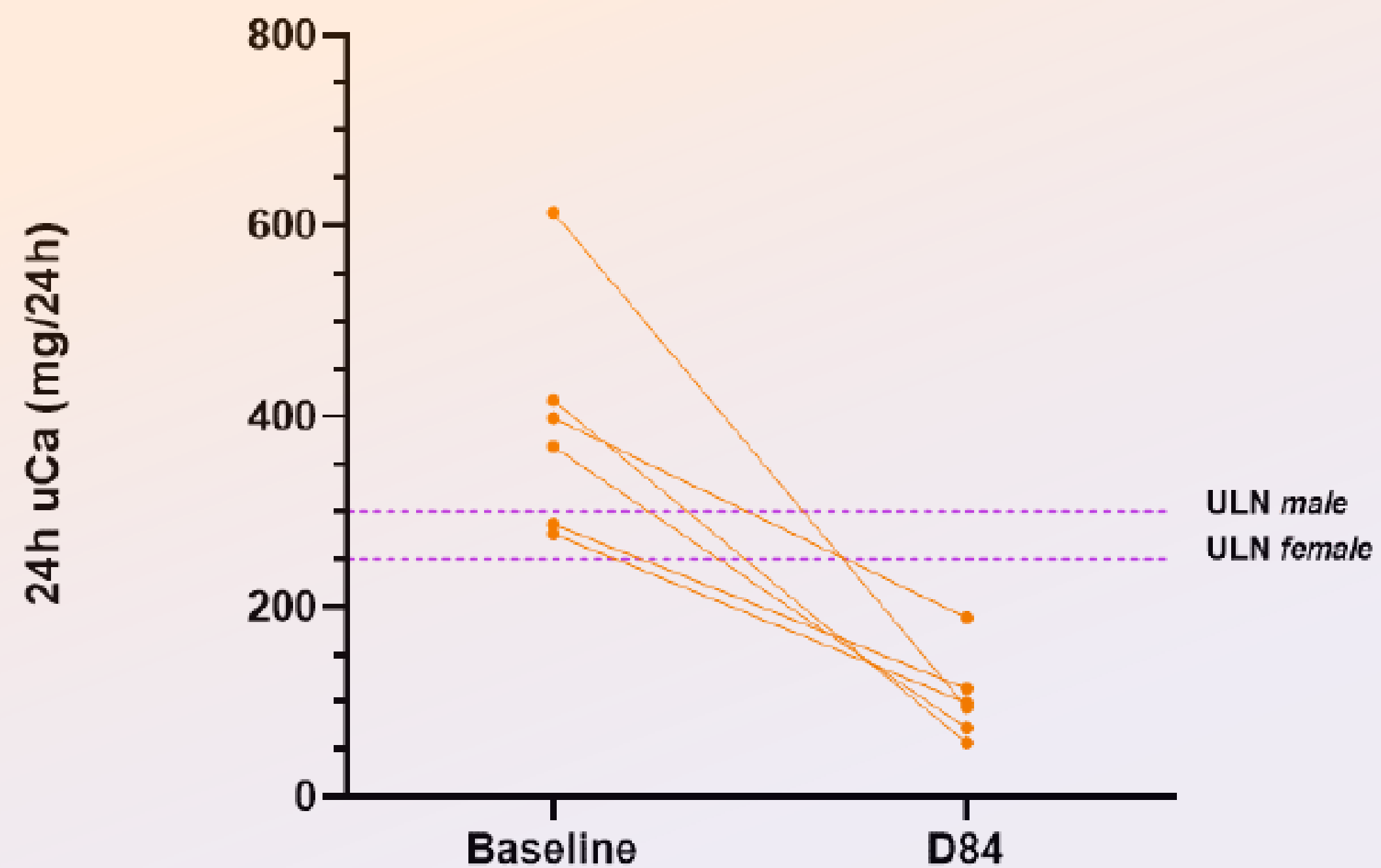


A**B**



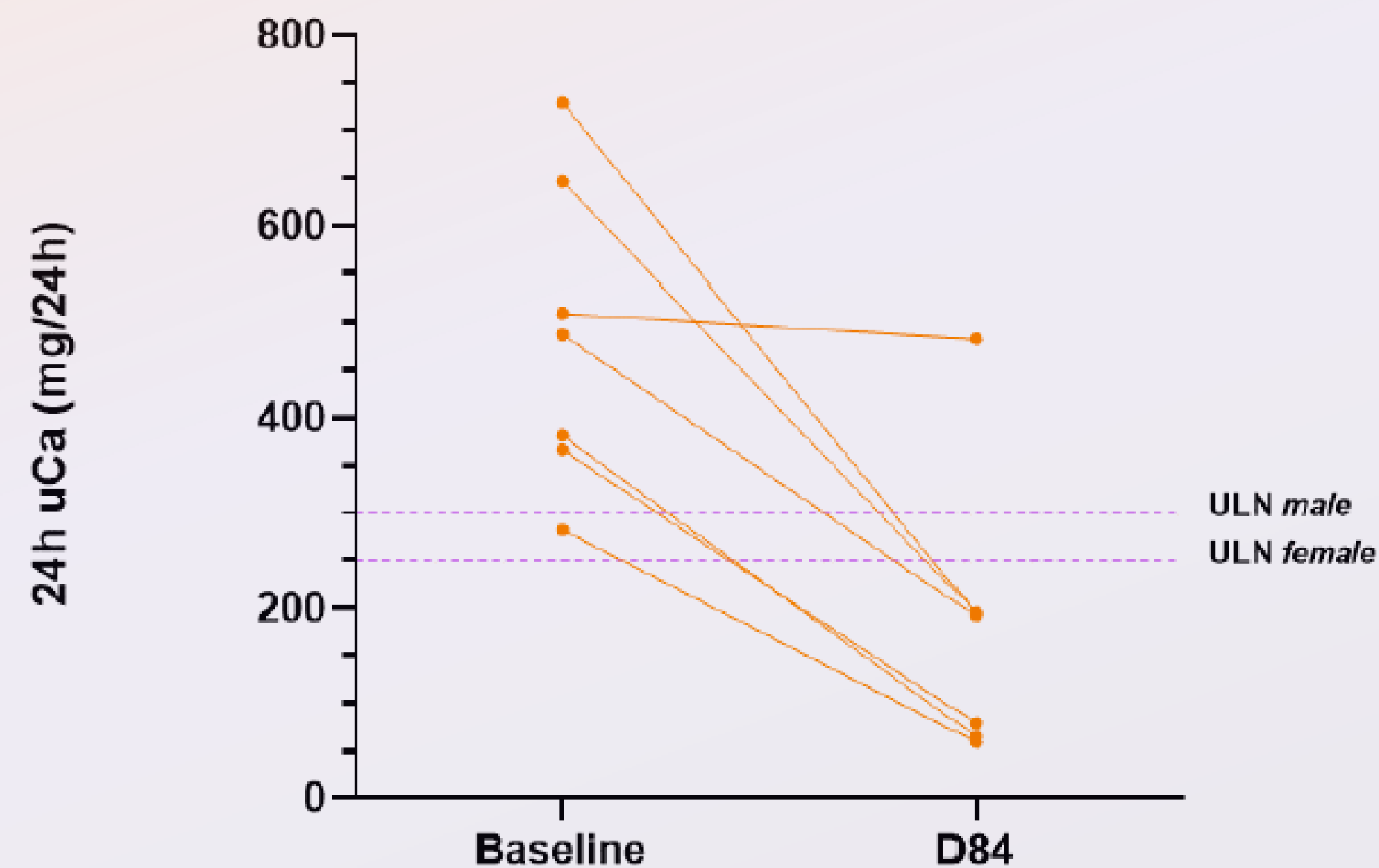
COHORT 1

C1 Patients with hypercalciuria at baseline, N=6



COHORT 2

C2 Patients with hypercalciuria at baseline, N=7



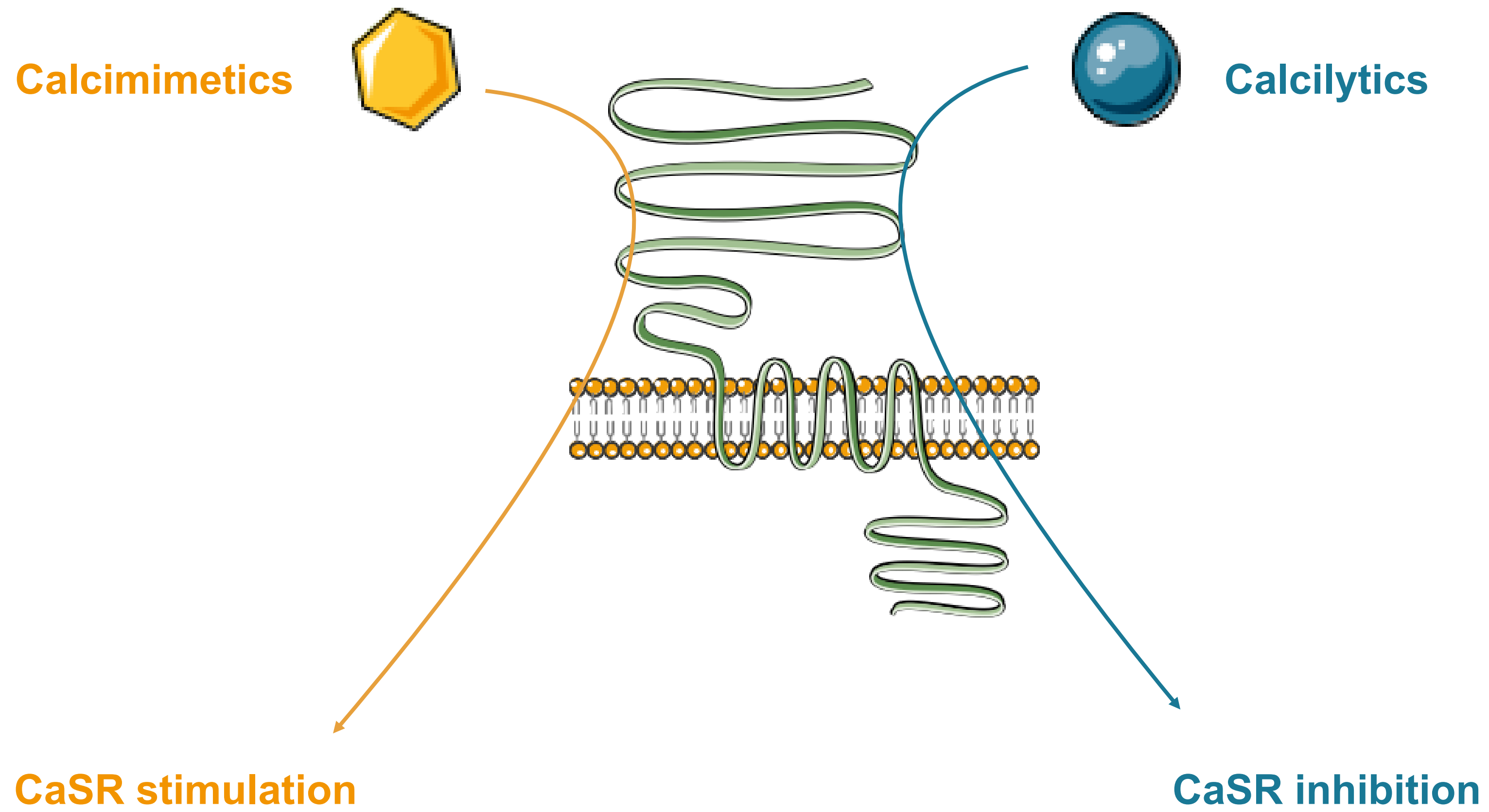
- Eneboparatide was well tolerated and no major adverse events were observed.
- 92% of the participants discontinued conventional therapy, while mean sCa was maintained within the target range.
- Mean uCa rapidly normalized in the majority of the patients.

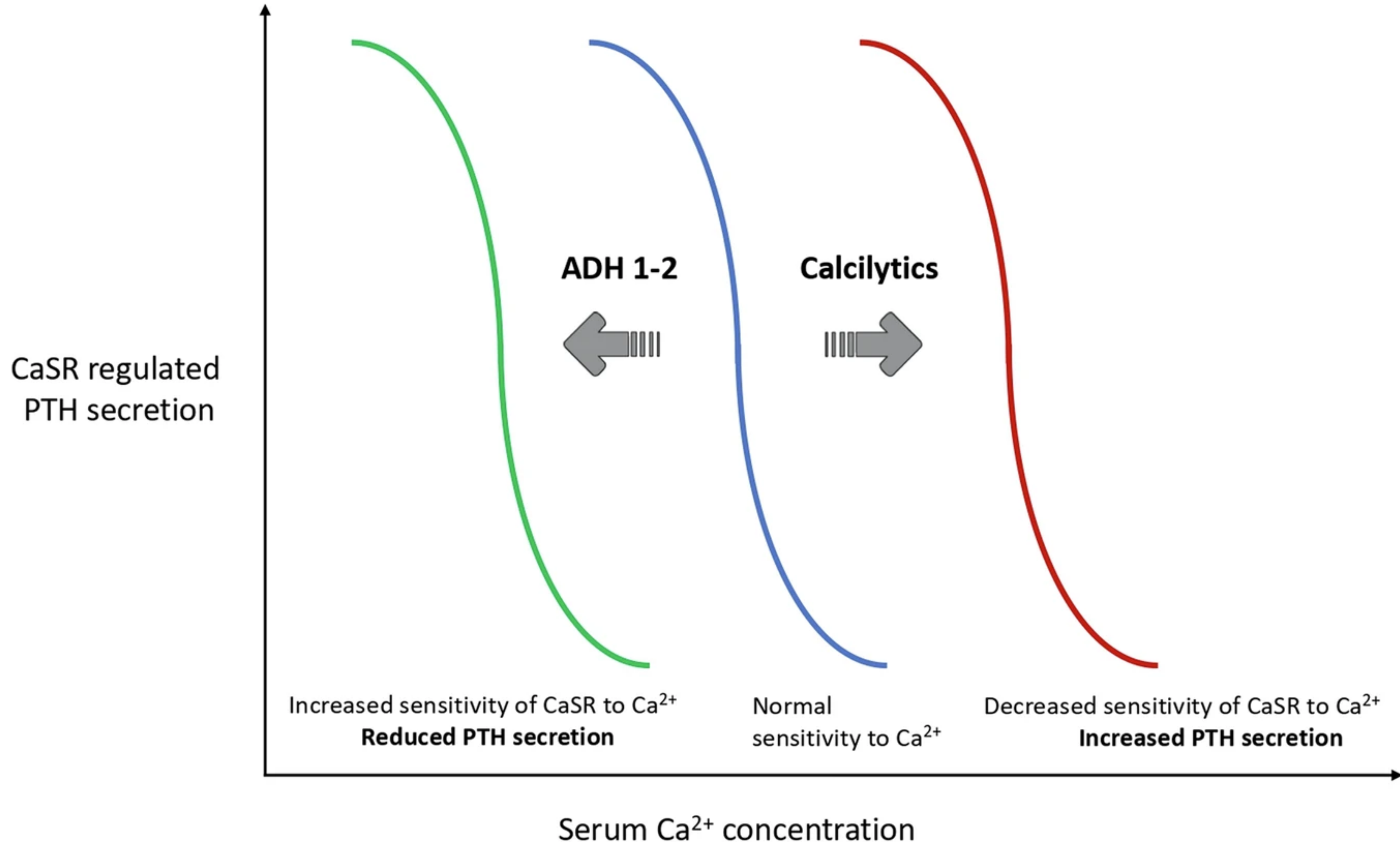
CALYPSO

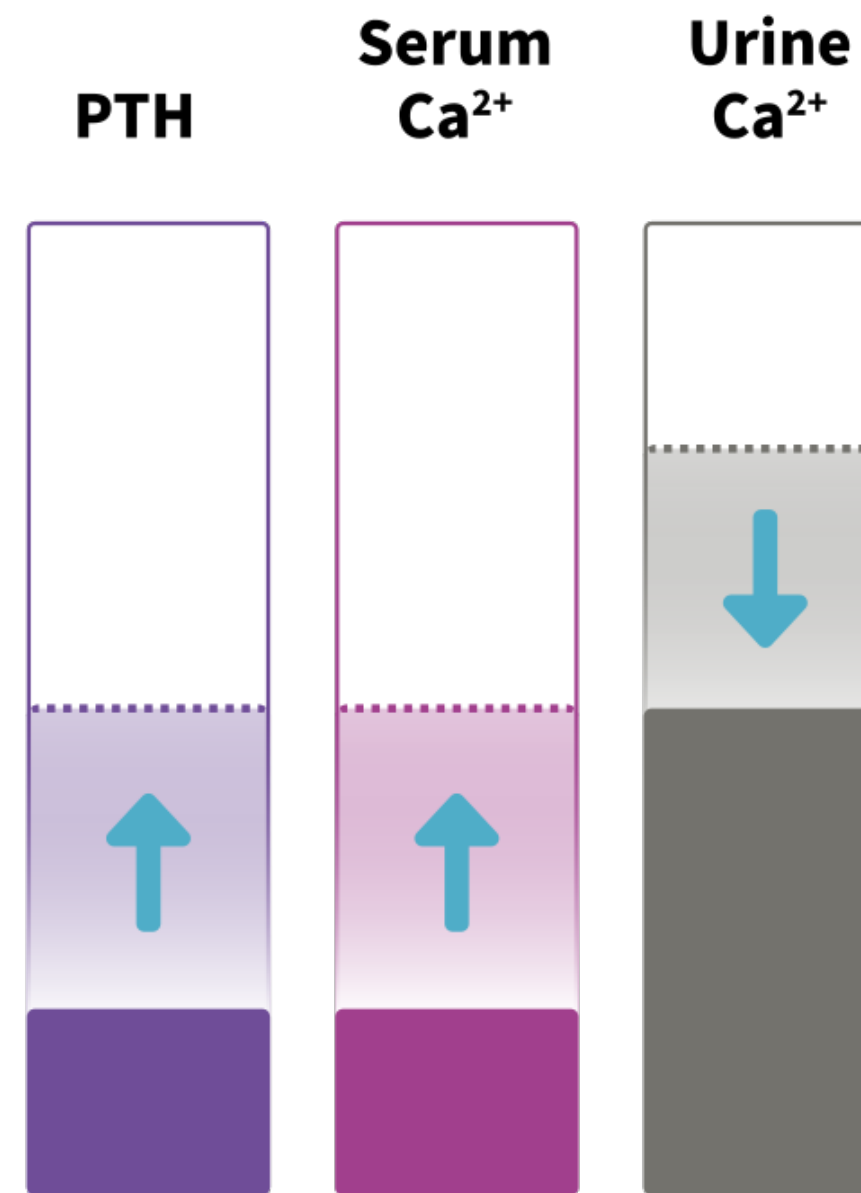
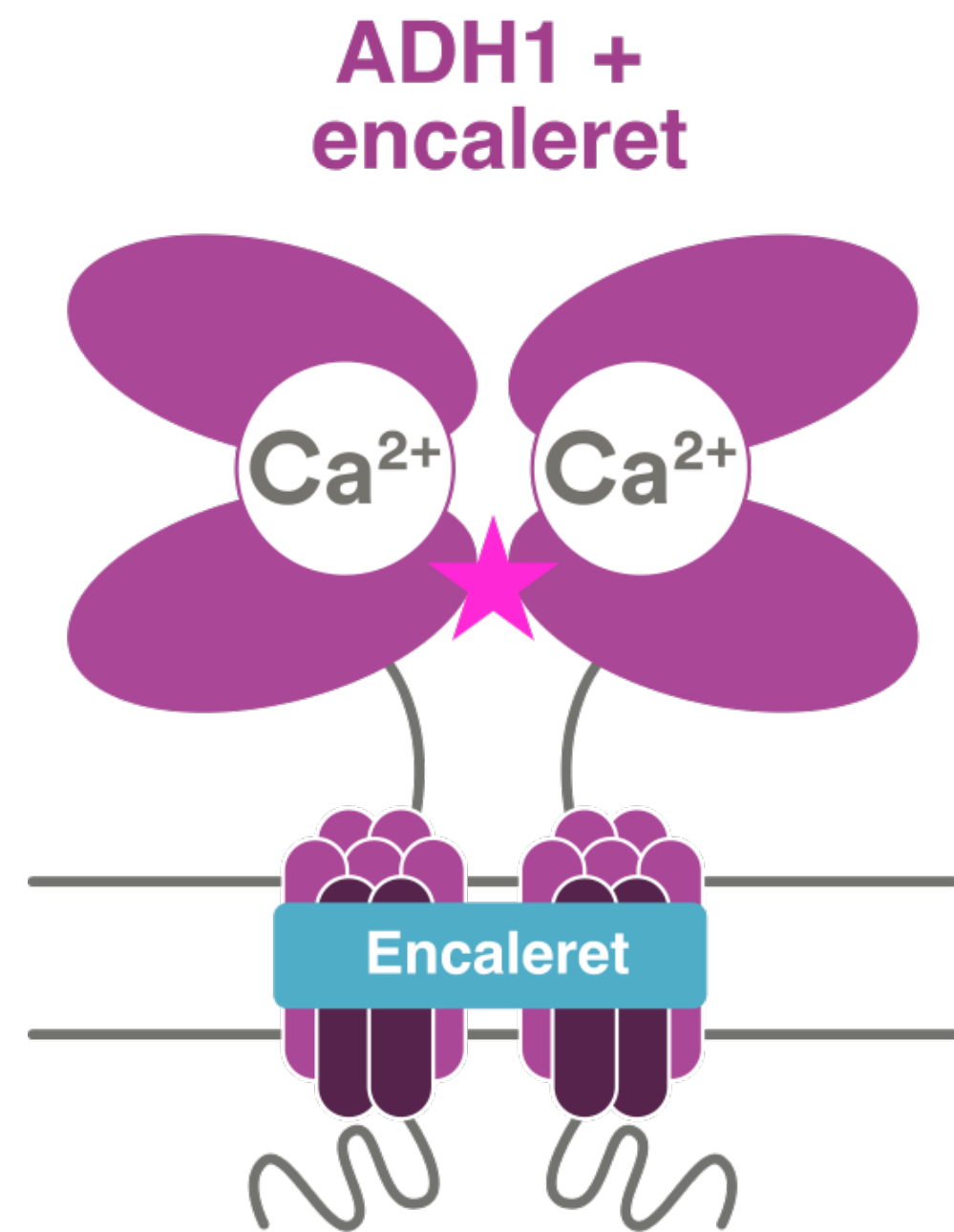
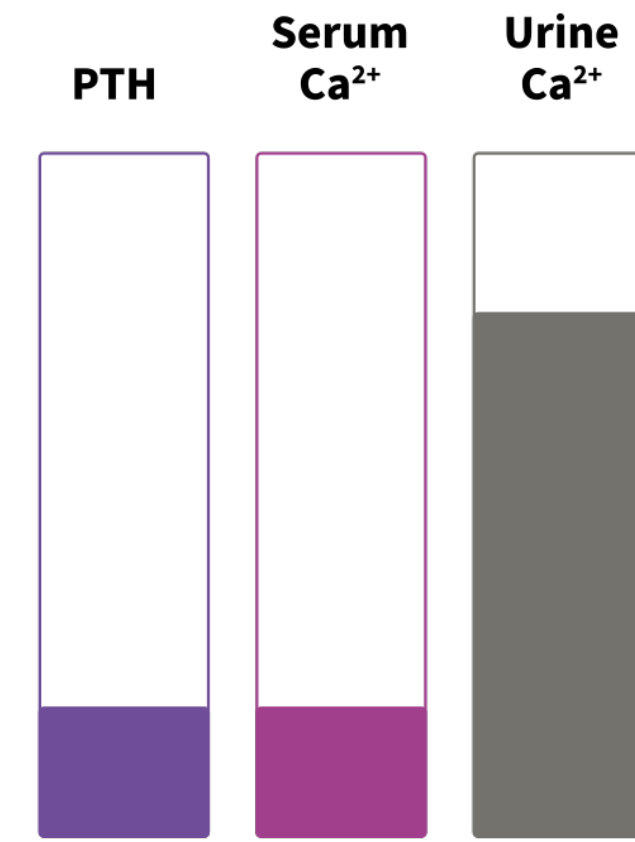
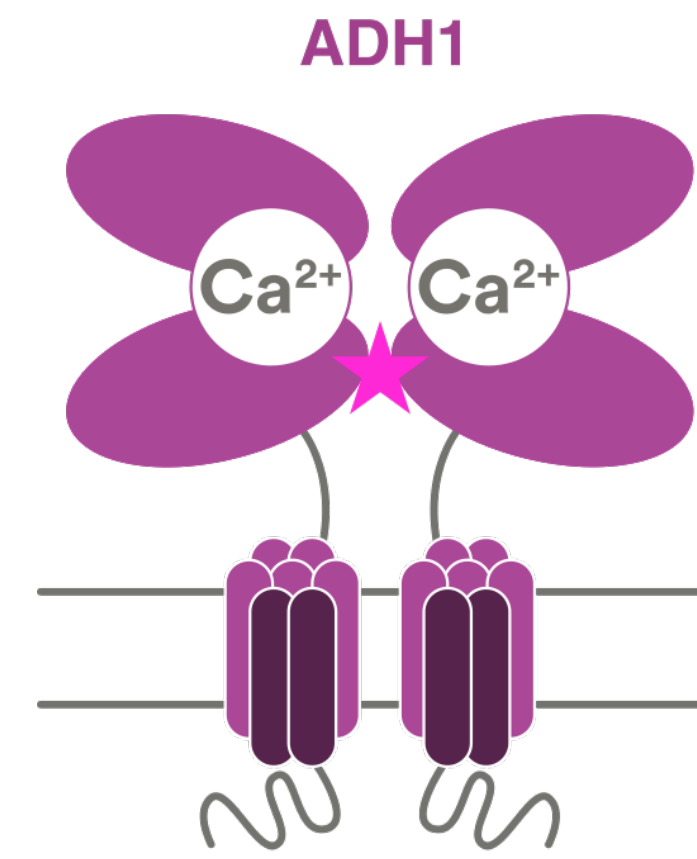
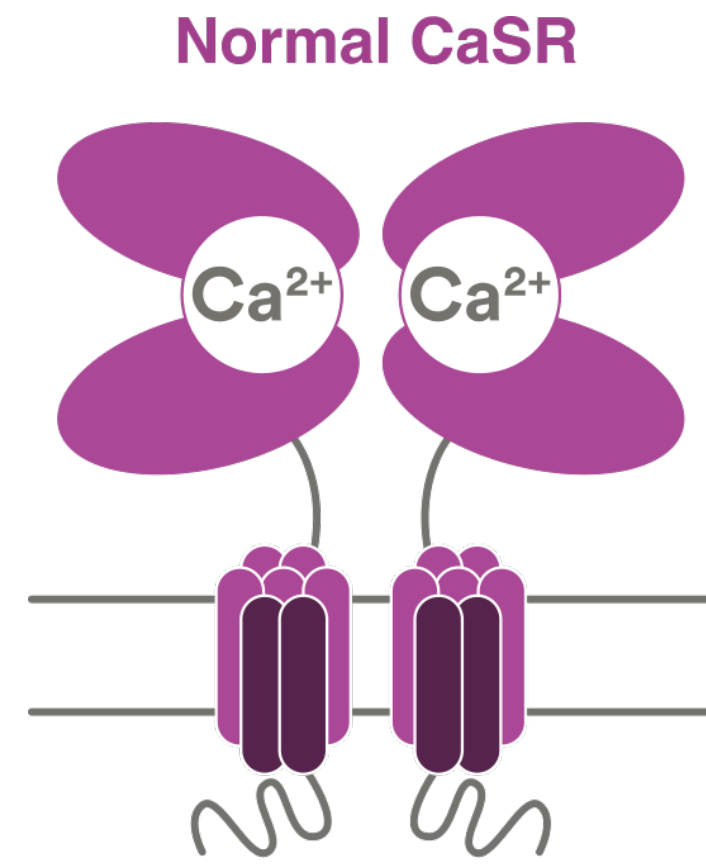
NCT05778071

- A Phase 3 Multicenter, Randomized, Placebo-controlled, Double-blind Study to Evaluate the Efficacy and Safety of Eneboparatide
- 54 locations
- Males and Females, 18-80 years of age
- Patients with CHP for ≥ 12 months at the time of screening
- Eneboparatide: Starting dose of 20 mcg, administered once daily by subcutaneous injection

Calcilytics



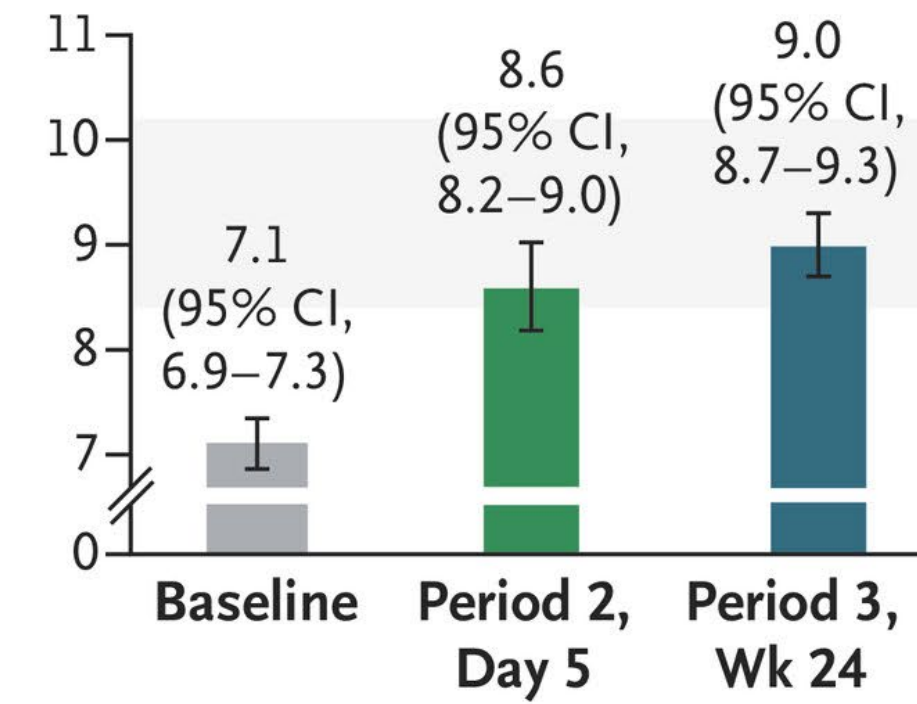
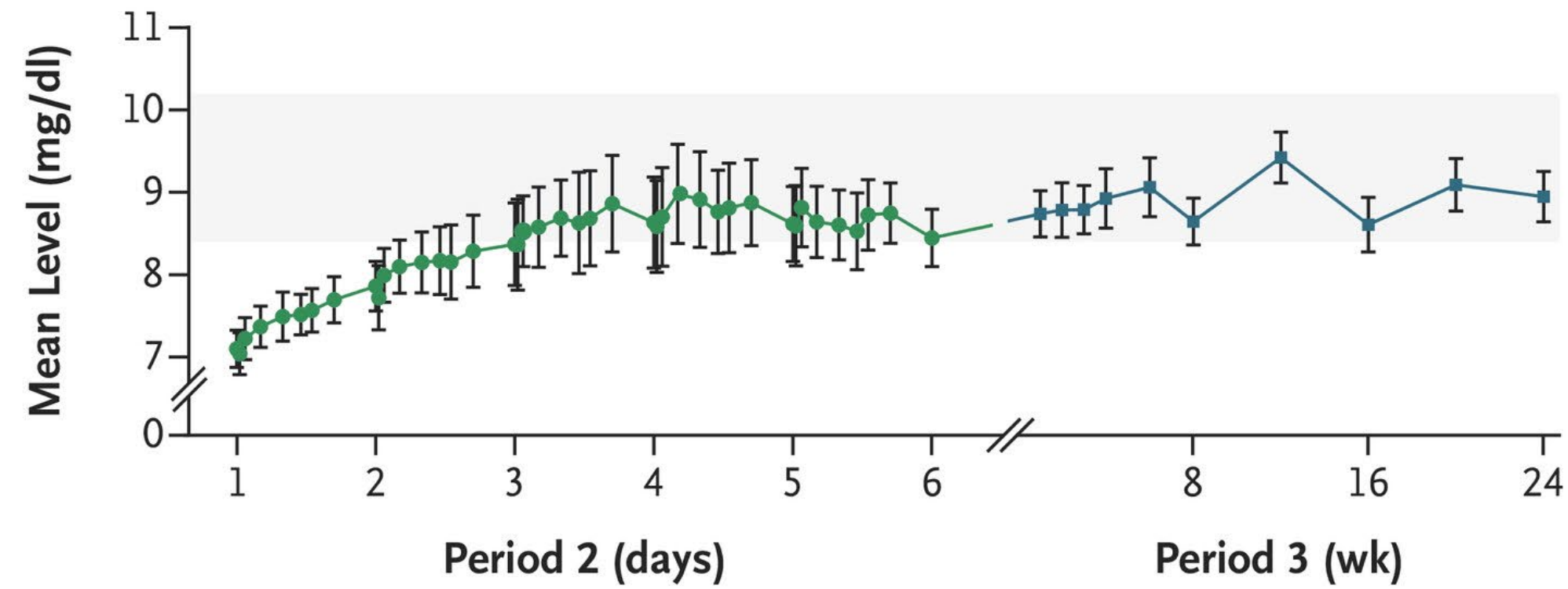




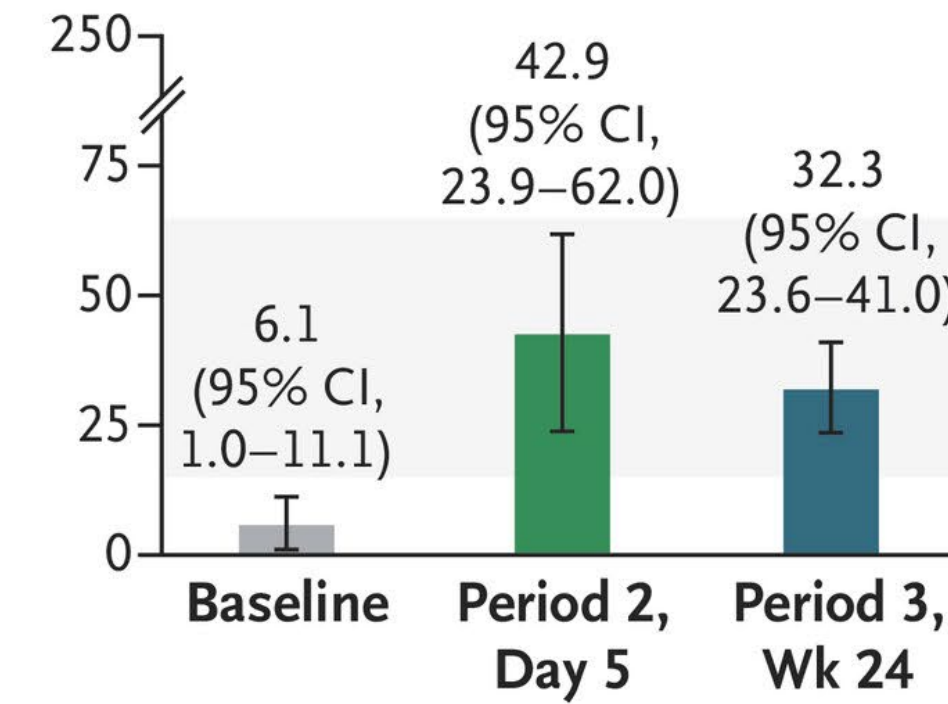
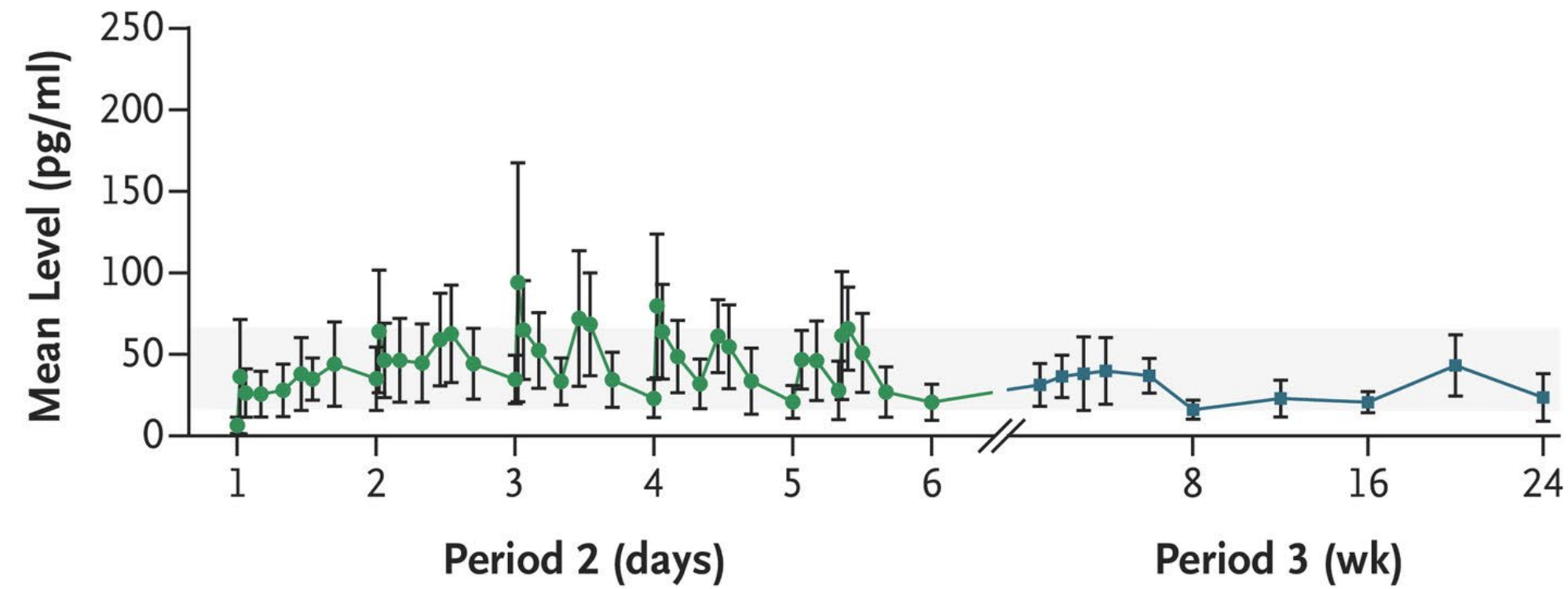
NCT04581629

- Safety, Tolerability, and Efficacy of Encaleret in Participants With Autosomal Dominant Hypocalcemia (ADH) Type 1
- Phase 2b study
- 1 location
- Males and Females
- Patients had an activating mutation of the Calcium-sensing receptor (CASR) gene and were treated with active vitamin D and Calcium

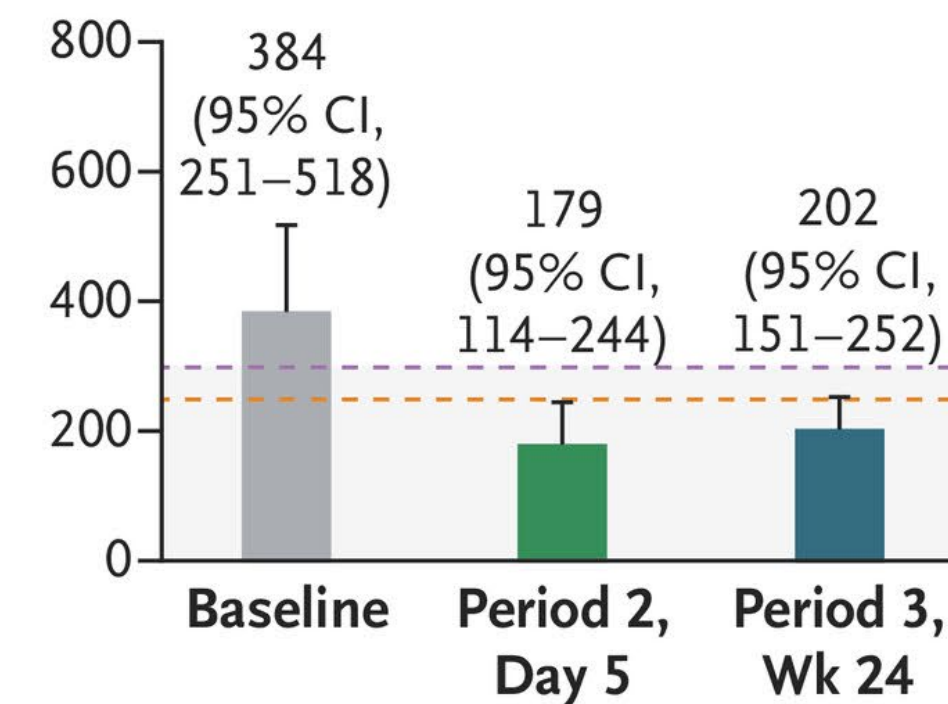
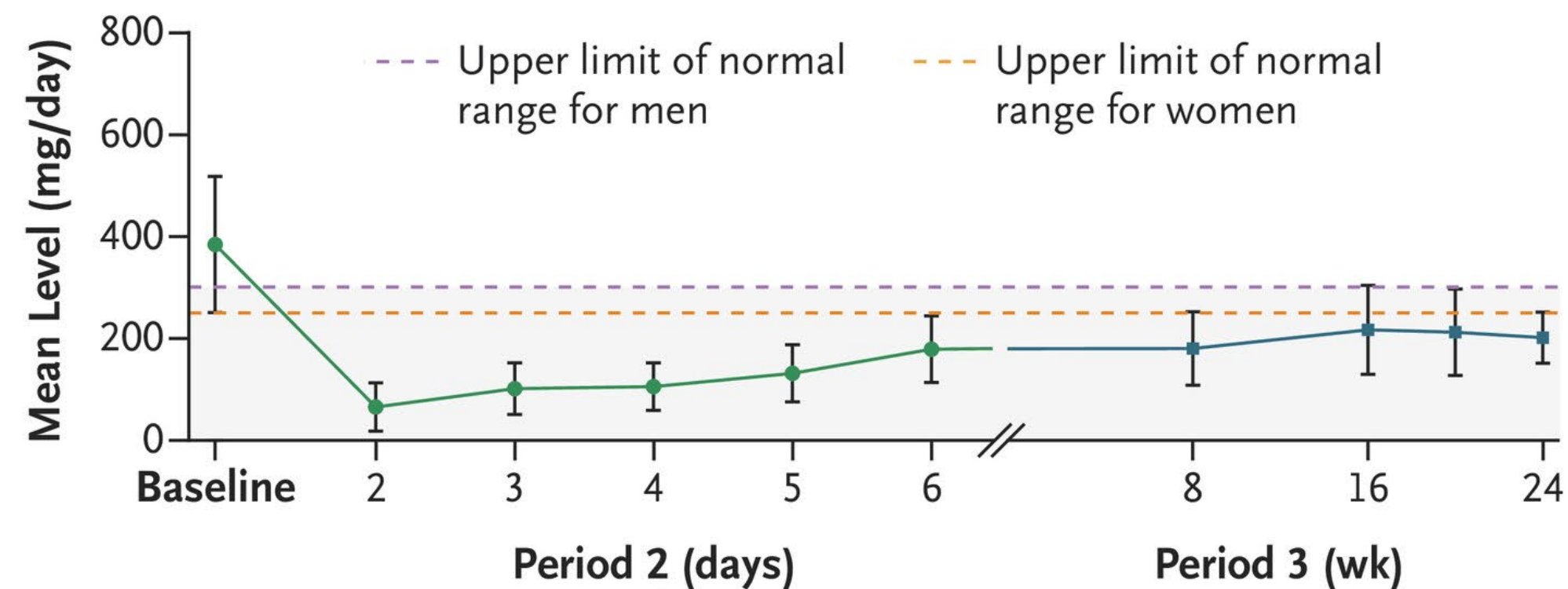
A Albumin-Corrected Blood Calcium Level



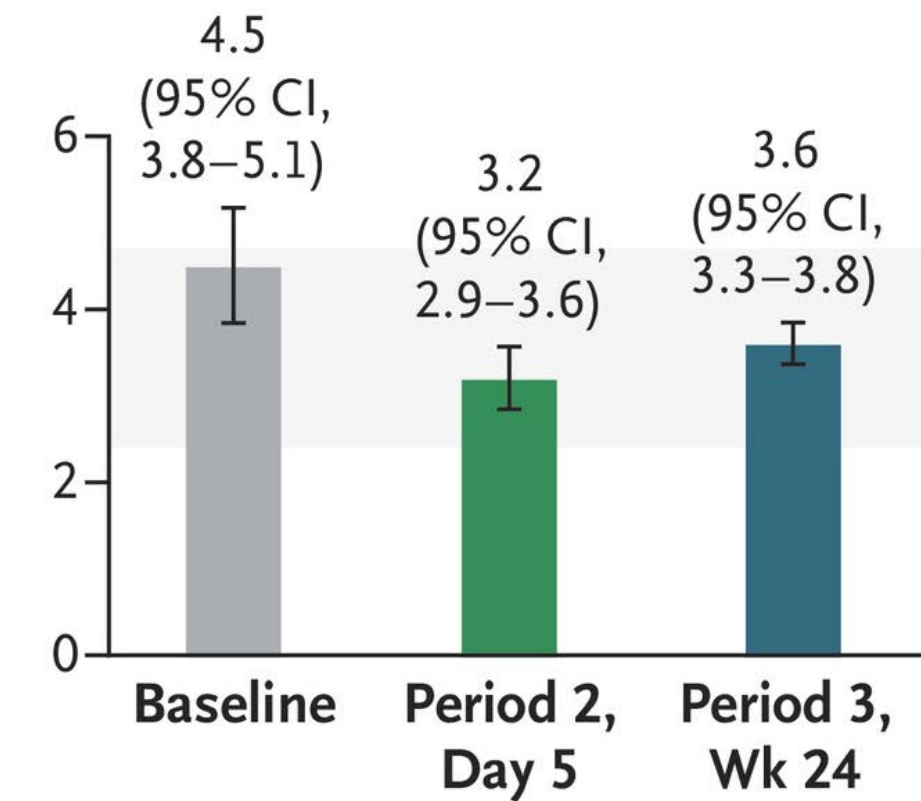
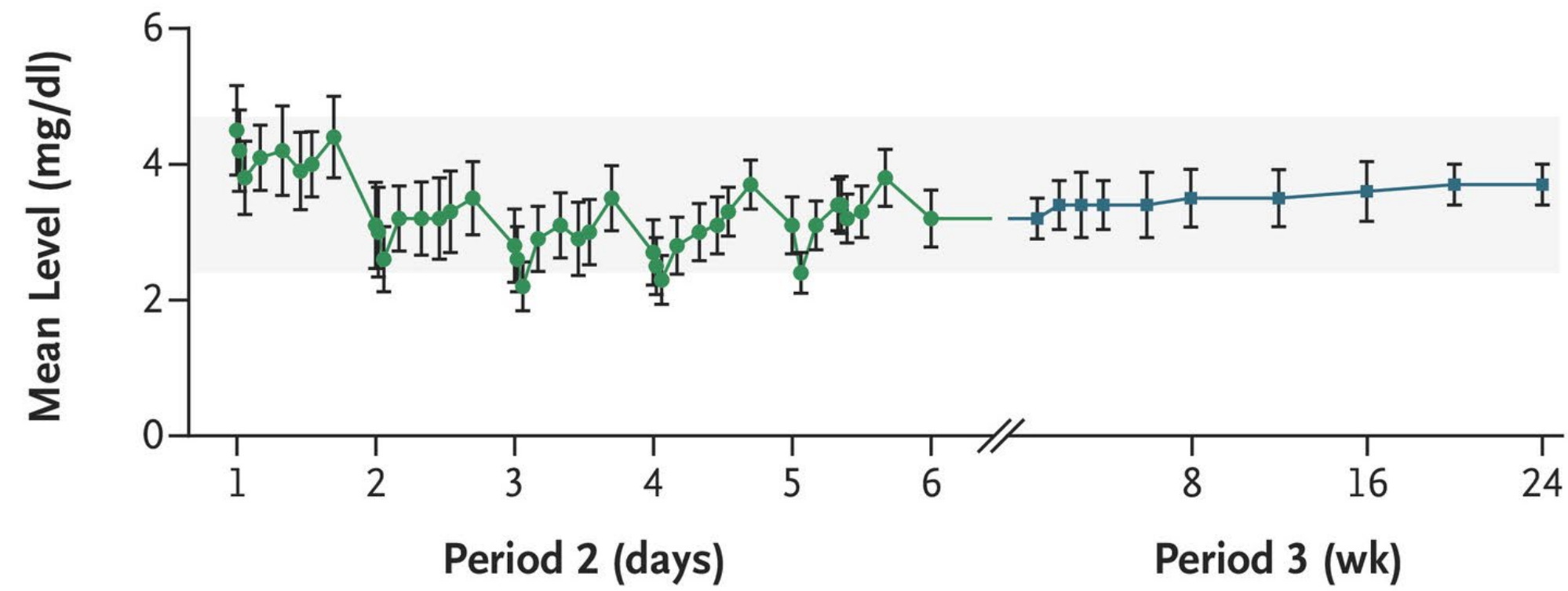
B Intact Parathyroid Hormone Level



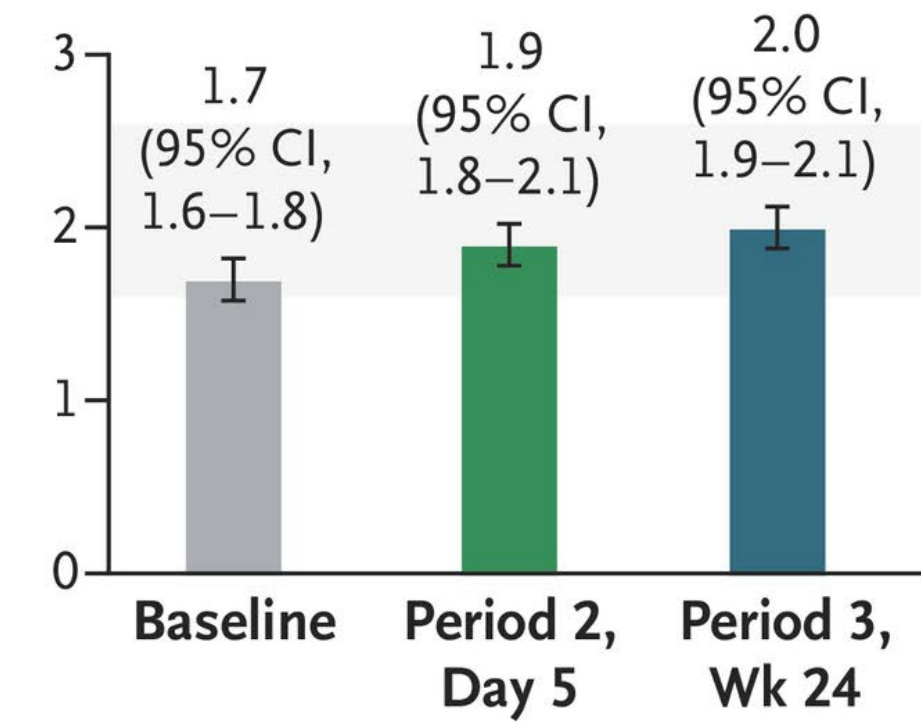
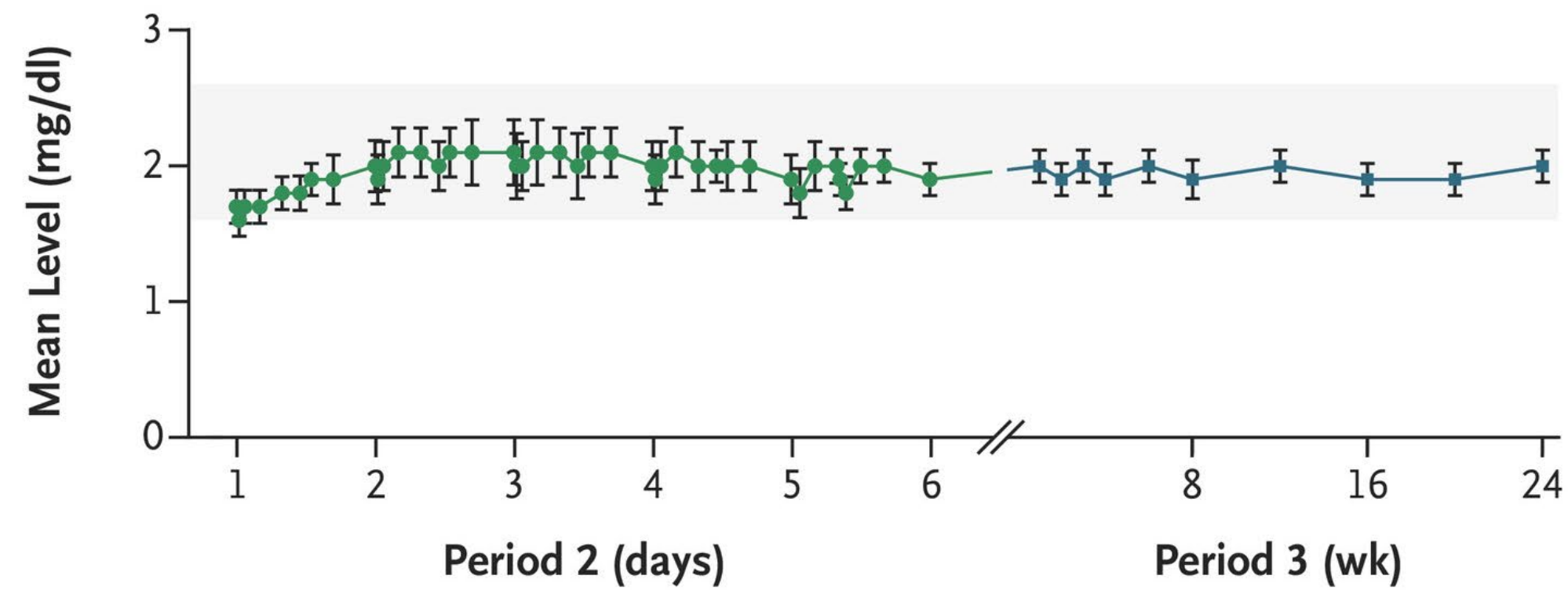
C Urinary Calcium Excretion



D Blood Phosphorus Level



E Blood Magnesium Level



- Encalaret was well tolerated and no major adverse events were observed.
- Treatment restored physiologic mineral homeostasis in all participants.
- Mean uCa normalized within 2 days of treatment.

CALIBRATE

NCT05680818

- A Phase 3, Randomized, Open-Label Study Evaluating the Efficacy and Safety of Encaleret Compared to Standard of Care in Participants With Autosomal Dominant Hypocalcemia Type 1 (ADH1)
- 25 locations
- Males and Females, 16-80 years of age
- Participants must have a documented pathogenic or likely pathogenic activating variant, or variant of uncertain significance, of the calcium sensing receptor (CASR) gene associated with biochemical findings of hypoparathyroidism
- Encaleret given orally at a variable dose according to their Ca concentration