



Abstract

Can Milk-Derived Calcium Permeate Attenuate Loss of Bone Mineral Density in Postmenopausal Women? The 12 mo RENEW Randomized Intervention Study [†]

Inge Tetens ^{1,*}, Sidse Ida Ingemann Rasmussen ¹, Mai Østerø Cramon ², Caroline Filskov Petersen ¹, Sadime Basak Kisi Kaki ¹ and Mette Friberg Hitz ²

¹ Department of Nutrition, Exercise and Sports, University of Copenhagen, 1958 Frederiksberg C, Denmark; sbkk@nexs.ku.dk (S.B.K.K.)

² National Research Center for Bone Health, Zealand University Hospital (ZUH), 4600 Køge, Denmark; maicr@regionsjaelland.dk (M.Ø.C.); mefh@regionsjaelland.dk (M.F.H.)

* Correspondence: ite@nexs.ku.dk

[†] Presented at the 14th European Nutrition Conference FENS 2023, Belgrade, Serbia, 14–17 November 2023.

Abstract: Background: An earlier study showed different metabolic responses to intake of an acute calcium load from milk-derived calcium permeate (CP) and calcium carbonate (CC). The long-term and clinical implications for bone maintenance are unknown. Objective: To investigate the effects of 12-month supplementation with CP, taken alone or in conjunction with inulin, on changes in bone mass density (BMD) and bone turnover markers (BTMs) in apparently healthy postmenopausal women compared with CC or placebo. Methods: A 12-month randomized controlled double-blinded multi-center intervention trial was conducted with healthy postmenopausal women with adequate vitamin D status. During the trial, participants received maltodextrin (placebo), 800 mg calcium as CC, or 800 mg calcium as CP (Capolac[®]MM-0525 BG, Arla Foods Ingredients Group P/S, Viby J, Denmark) without or with 12 mg of inulin and divided into two daily doses of capsules and sachets. A daily vitamin D supplement of 20 µg was provided. At baseline and at the end of the study, BMD was assessed by DXA scan, and anthropometric measures were obtained together with fasting blood samples for measurements of BTMs (CTX and P1NP), serum iPTH, vitamin D, serum calcium, creatinine, phosphate, and triglycerides. Habitual dietary intake was assessed using the online system Myfood24, where subjects recorded their dietary intake for 7 consecutive days, and physical activity was assessed by the International Physical Activity Questionnaire. Socioeconomic data and physical activity were obtained through questionnaires. Preliminary results: A total of 417 women were eligible according to the inclusion and exclusion criteria and were included over a 12-month period. At present, 239 subjects have completed the study. The intervention will end in June 2023. Baseline characteristics (mean ± SD) are age 55.4 ± 4.17 years; height 167.4 ± 5.73 m; body weight 71.5 ± 11.7 kg; BMI 25.5 ± 3.78; hip circumference 102.3 ± 9.48 cm; and waist circumference 84.09 ± 10.0 cm. The BMDs expressed as t-scores were L-total −0.46 ± 1.17 and Neck-total −0.88 ± 0.80. Discussion: The recruitment of eligible participants was delayed due to COVID but was successful within one year. The drop-out rate has been larger than expected. More results will be ready to be presented at the conference.

Keywords: calcium carbonate; calcium supplementation; inulin; bone mass density; BMD; CTX; P1NP; RCT; diet; myfood24



Citation: Tetens, I.; Rasmussen, S.I.I.; Cramon, M.Ø.; Petersen, C.F.; Kaki, S.B.K.; Hitz, M.F. Can Milk-Derived Calcium Permeate Attenuate Loss of Bone Mineral Density in

Postmenopausal Women? The 12 mo RENEW Randomized Intervention Study. *Proceedings* **2023**, *91*, 192.

<https://doi.org/10.3390/proceedings2023091192>

Academic Editors: Sladjana Sobajic and Philip Calder

Published: 2 February 2024



Copyright: © 2024 by the authors. Licensee MDPI, Basel, Switzerland. This article is an open access article distributed under the terms and conditions of the Creative Commons Attribution (CC BY) license (<https://creativecommons.org/licenses/by/4.0/>).

Author Contributions: Conceptualization, design and methodology: I.T. and M.F.H.; Investigation: S.I.I.R., M.Ø.C., C.F.P. and S.B.K.K.; Resources: I.T. and M.F.H. All authors have read and agreed to the published version of the manuscript.

Funding: The study is financially supported by Innovation Fond Denmark (Grand Solutions 2019, *Grant No. 9090-00017B). The foundation has no commercial interest in the project.

Institutional Review Board Statement: The regional ethics committee approved the trial protocol (10286258), and the trial was registered at clinicaltrials.gov (NCT04836637).

Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

Data Availability Statement: Data are still being generated and are therefore unavailable at the present timepoint.

Conflicts of Interest: The authors report no conflicts of interest.

Disclaimer/Publisher's Note: The statements, opinions and data contained in all publications are solely those of the individual author(s) and contributor(s) and not of MDPI and/or the editor(s). MDPI and/or the editor(s) disclaim responsibility for any injury to people or property resulting from any ideas, methods, instructions or products referred to in the content.