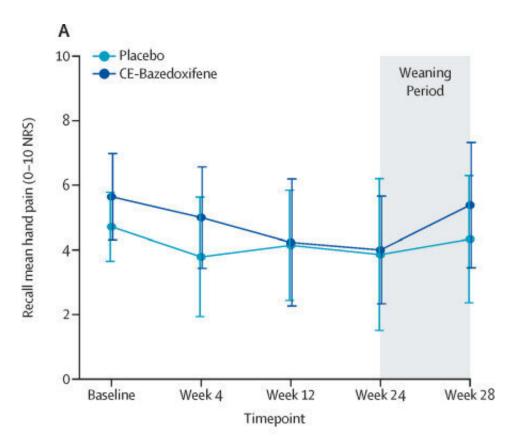


Assessing the feasibility of hormone replacement therapy for post-menopausal women with hand osteoarthritis

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Change in mean hand pain in participants over the study period. (A) Recall at



study visits of mean hand pain on a 0–10 NRS for the preceding 14 days before the baseline, and week 4, 12, 24, and 28 study visits. (B) Mean of recorded daily mean hand pain on a 0–10 NRS for the preceding 14 days before the baseline, and week 4, 12, and 24 study visits (not collected at week 28). The point is the mean and error bars represent the SD. (C) Patient-reported category of change in hand pain for the preceding 14 days before the week 28 study visit (following weaning from study medication), by treatment allocation. The proportion within the category is shown on bars. CE-bazedoxifene=conjugated oestrogens plus bazedoxifene. NRS=numerical rating scale. Credit: *The Lancet Rheumatology* (2022). DOI: 10.1016/S2665-9913(22)00218-1

A recent study to test the feasibility of running a randomized controlled trial of hormone replacement therapy (HRT) for post-menopausal women with hand osteoarthritis, has produced positive results. The HOPE-e feasibility study paves the way for researchers to design a full trial.

Hand osteoarthritis affects 40% of people over their lifetime and for many it causes high levels of pain and reduced quality of life. It is more common in women and there is a noticeable rise in cases around the age of 50 years, one theory being that the estrogen deficiency around the time of the menopause fuels the onset or progression of the symptoms associated with the condition.

However, no trials of <u>hormone</u> replacement therapy (HRT) have yet been done in osteoarthritis so researchers at NDORMS set out to see if a randomized controlled trial would be feasible.

"The aims of the study were to test whether women would want to join a study like this, refine how we would run a full trial and generate important proof of concept data. This was a small randomized clinical trial using a particular type of HRT to treat painful hand osteoarthritis in



post-menopausal women," said Trial Manager, Jenny Williams. "It wasn't designed to test for a clinical effect, but the insights we gained from this study suggest that a full trial would be feasible."

Twenty-eight eligible participants were recruited to the HOPE-e trial and randomly assigned either a form of HRT (conjugated oestrogens plus bazedoxifene) or a placebo. The primary report from the study, published in *The Lancet Rheumatology*, showed that all the primary feasibility outcomes could be met and progression to a full trial would be supported.

"The results of the HOPE-e feasibility study adds to a growing body of evidence that shows the importance of considering sex hormones and lifecourse in osteoarthritis and in other musculoskeletal conditions in women," said Fiona Watt, Honorary Departmental Senior Fellow.

Author of a recent related Viewpoint piece in *The Lancet Rheumatology* exploring "the influence of sex hormones on musculoskeletal pain and osteoarthritis," following this work, Fiona explains that changes to hormone balance either by natural, surgical, autoimmune or by the use of medications, appear to be a factor which can drive musculoskeletal pain.

Working with some of those on the Oxford HOPE-e team (Katy Vincent, Malvika Gulati) this review synthesizes evidence from studies conducted over the last 7 years. "More research in this area could be a game-changer for better understanding of sex differences in the condition and potentially developing sex-specific considerations for the treatment of painful musculoskeletal conditions like <u>osteoarthritis</u>."

More information: Jennifer A E Williams et al, Hormone replacement therapy (conjugated oestrogens plus bazedoxifene) for postmenopausal women with symptomatic hand osteoarthritis: primary



report from the HOPE-e randomised, placebo-controlled, feasibility study, *The Lancet Rheumatology* (2022). DOI: 10.1016/S2665-9913(22)00218-1

Malvika Gulati et al, The influence of sex hormones on musculoskeletal pain and osteoarthritis, *The Lancet Rheumatology* (2023). DOI: 10.1016/S2665-9913(23)00060-7

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