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## ROmosozumab Loaded with EXercise-DUal effects on bone and muscle in Osteoporosis (ROLEX-DUO)

### Investigating the best approach of multidisciplinary care for older Australians with osteoporosis by combining drug and exercise treatment

Osteoporosis is a state of increased bone fragility where affected individuals are more prone to fractures. A fragility fracture is a fracture resulting from a fall from standing height (or less). Given our aging population, and the devastating health impacts a fracture can have, innovative ways to optimise the treatment of osteoporosis are needed.

Romozumab is an anti-sclerostin monoclonal antibody which increases bone formation and has been shown to be effective in treating osteoporosis. Romozumab may also have clinically important effects on muscle health. Exercise and romozumab both promote bone formation through similar mechanisms and simultaneous treatment may provide additive benefits.



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"Our study will be the first to investigate effects of romozumab on muscle and physical performance in humans and the first RCT to investigate this for any osteoporosis drug. This is relevant for people with osteoporosis as improvements in muscle and physical performance may reduce the risk of falls," says Dr Kumar.

### How is this study being conducted

The study is a multi-centre RCT in women with post-menopausal osteoporosis to determine whether bone-strengthening exercise can increase the effects of the bone-building drug romozumab in improving bone mass over 12 months. The researchers will also assess whether romozumab can improve muscle mass, strength and physical function, which may reduce risk of falls.

"The primary aim of the study is to determine if combining romozumab with high-intensity exercise promotes greater improvements in bone mineral density (BMD) than romozumab with low-intensity exercise in postmenopausal women with osteoporosis," explains Dr Kumar.

BMD is a well-established marker for risk of fragility fractures in postmenopausal women with osteoporosis, a chronic debilitating condition with significant economic and health burden in Australia. Implementing this combination of bone-building exercise and medication has never been studied and may represent the most effective strategy to improve BMD in people with osteoporosis.

### Looking ahead

"Results of the study will help clinicians determine if they should prescribe bone-building exercise with romozumab to enhance the treatment response," says Dr Kumar.

Longer-term aims are increased global interest in investigating the combination of exercise with osteoporosis medication. The researchers also envision a future with enhanced collaboration between osteoporosis doctors, general practitioners, exercise physiologists and physiotherapists to deliver the best multidisciplinary care for older Australians with osteoporosis.

*Dr Shejil Kumar is an Early Career Research Program award recipient, and is currently enrolled in a PhD program with the University of Sydney and is training to become an Endocrinologist.*