

Can Calcium and Vitamin D reduce diabetes risk in people at high risk?

ACTRN12609000043235

Status	RECRUITING
Phase	Phase 4
Sponsor	Professor Peter Ebeling
Enrollment	160 participants

Plain Language Summary

This study is testing whether taking vitamin D and calcium supplements can lower the risk of developing type 2 diabetes in people who are already at high risk. Type 2 diabetes is Australia's fastest-growing chronic disease. Researchers have noticed that low vitamin D levels may be linked to a higher chance of developing diabetes. Over 6 months, participants will take either vitamin D and calcium supplements or placebos (inactive pills) to find out if the supplements reduce diabetes risk and improve heart health.

You may be eligible if:

- You are 18 years or older
- You are overweight or obese (BMI between 25 and 35 kg/m²)
- You have been found to have pre-diabetes (impaired fasting glucose or impaired glucose tolerance)
- You are deficient in vitamin D

You may NOT be eligible if:

- You are pregnant or breastfeeding
- You have kidney disease, cirrhosis, or malabsorption problems
- You have high blood calcium or a history of kidney stones
- You have an active inflammatory disease
- You have recently changed diabetes-related or weight medications
- You have had or are planning bariatric (weight loss) surgery
- Your weight has changed by more than 5% in the past 3 months

Talk to your doctor about whether this trial might be right for you.

Key Eligibility Criteria

Inclusion (1)

- Vitamin D deficiency; overweight or obese as defined by a body-mass index (BMI) between 25-35 kg/m²; impaired fasting glucose or impaired glucose tolerance confirmed with a 75g 2h oral glucose tolerance test (OGTT).

Exclusion (1)

- Pregnancy; Breast-feeding; Renal insufficiency; Cirrhosis; Malabsorption; Hypercalcemia; Hypercalciuria; History of nephrolithiasis; Previous non-traumatic fractures; Active or chronic inflammatory disease; Medications known to affect vitamin D, calcium or bone metabolism over the last 3 months; Pharmacological treatment for obesity or medications known to alter glucose metabolism over the last 3 months; Bariatric surgery planned in the next six months or patients who had undergone bariatric surgery in the past; Commenced regular physical activity (more than 3 times/week) in the last 3 months; More than a 5% change in weight in the last 3 months.

Locations (1 total)

<http://australia.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12609000043235>

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