

Elucidating the Effects of Tocotrienol rich Vitamin E on Metabolic Biomarkers in a Pre-diabetes Population in Malaysia.

ACTRN12622000256774

Status	RECRUITING
Phase	Phase 2
Sponsor	Monash University Malaysia
Enrollment	80 participants

Plain Language Summary

Pre-diabetes is a stage where blood sugar levels are higher than normal but not yet high enough to be called type 2 diabetes. Without intervention, many people with pre-diabetes go on to develop full diabetes. Vitamin E — specifically a form called tocotrienol — has shown early promise in improving how the body responds to insulin, but more evidence is needed.

This Malaysian study is testing whether taking 200mg per day of tocotrienol-rich Vitamin E supplements helps to improve insulin sensitivity and blood sugar control in people with pre-diabetes. Half of participants will receive the supplement and half will receive a dummy pill (placebo), and neither participants nor researchers will know who received which until the study ends.

You may be eligible if you are between 40 and 75 years old, are of Malaysian Chinese, Malay or Indian background, have a pre-diabetes HbA1c reading of 5.7–6.4%, and score 15 or above on a diabetes risk assessment tool. People with established diabetes for 5+ years, poorly controlled blood pressure, pregnancy, serious illness, kidney disease, or who are currently taking other vitamin supplements are not eligible.

Key Eligibility Criteria

Inclusion (4)

- Multi-ethnic population in Malaysia namely, Chinese, Malay and Indian who are 40 years and above with high risk of Diabetes Mellitus/Pre-diabetes with a FINDRISC Score of 15 and above i.e. risk of diabetes 33%. (Follow the FINDRISC Model)
- A risk score of 15 to 20 points indicates a high risk of diabetes (33% chance of diabetes over 10 years).
- A risk score of greater than 20 points indicate a very high risk of diabetes (50% chance of diabetes over 10 years).
- Pre-Diabetes criteria: HbA1c: 5.7 to 6.4% (revised)

Exclusion (16)

- FINDRISC score lower than 15 and HbA1c greater than 6.5% for pre diabetes, and greater than 8.0% for new diabetes
- Diagnosed diabetes patients for 5 years or more.
- Fluctuating blood sugar level
- Unstable glucose control (more than 10% change in HbA1c levels over the last 2 months)
- High blood pressure
- ... and 11 more (see full listing online)

Locations (2 total)

Kota Damansara, Selangor, Malaysia
Faculty of Medicine and Health Sciences, 43400 UPM Serdang, Selangor Darul Ehsan., Malaysia

<https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12622000256774>

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