



**RECRUITMENT
CLINICAL TRIAL
PHASE III**

**Sailuotong for
Vascular Dementia
or Alzheimer's
Disease with
Cerebrovascular
Disease**

NICM
Health Research Institute

**WESTERN SYDNEY
UNIVERSITY**



Vascular dementia (VaD) is the second major cause of dementia accounting for 15-20% of all dementia cases. VaD is an acquired cognitive impairment due to multiple mini strokes, some of which may be undetectable to the patient. The result is memory loss and a decline in cognitive ability. Currently, viable pharmaceutical options are lacking.

This phase III clinical trial is investigating the efficacy and safety of a standardised Chinese herbal formula, Sailuotong (SLT) for vascular dementia or mixed dementia (Alzheimer's disease with cerebrovascular disease).

SLT, a complex combination of ginseng, ginkgo and saffron extracts, has been scientifically developed and tested by a combined team from China Academy of Chinese Medical Sciences and NICM Health Research Institute at Western Sydney University. Over the last 10 years, SLT has been systematically studied in the laboratory and clinical trials. Data from pre-clinical studies have shown significant improvements in cognitive functions and in various pathological tests.¹ A recent phase II clinical trial reported improved functioning in multiple cognitive domains, such as memory, orientation, language and executive function after 26 weeks of SLT treatment in 325 Chinese patients with mild-to-moderate vascular dementia.²

1 Chang et al.(2016). Evidence-based Complementary and Alternative Medicine, Volume 2016, Article ID 7293626.

2 Jia et al.(2018). Alzheimer's & Dementia: Translational Research & Clinical Interventions, 4 (2018), 108-117.

WHAT'S INVOLVED?

This clinical trial is a double-blinded study. Participants will be randomly assigned to receive the active study drug or placebo, and will be instructed to take it for a 52 week period. Over 65 weeks, participants will need to attend eight scheduled clinic visits where they will be assessed by the research team, have blood tests, and complete several questionnaires.

WHAT ARE THE BENEFITS TO PARTICIPATING?

Participants will be reimbursed for their travel costs at each clinic visit. When participants complete the trial, they are eligible to receive a 12 month complimentary supply of SLT and will have their health monitored during this time.

This trial supports dementia research and innovation and aligns with the World Health Organization's (WHO) Global action plan on the public health response to dementia 2017-2025; Towards a dementia plan: a WHO guide; the 2030 Agenda for Sustainable Development, in Promoting Health, Sustainable Development Goal 3 (good health and wellbeing); and the Australian Government National Framework for Action on Dementia 2015-2019. The researchers acknowledge the support of Shineway Pharmaceuticals for this study. This study has been approved by the Human Ethics Committees of Western Sydney University (Approval Number: H11554), South Western Sydney Local Health District Human Research Ethics Committee (HREC/14/LPOOL/81), the NSW Guardianship Tribunal (Approval Number: 1/2015), Specialist Services Medical Group Research and Ethics Committee, Southern Cross University Ethics Committee (ECN-17-221).

WHO CAN JOIN?

- Men and women over 40 years who can understand, read and write basic English
- Participants who have been diagnosed with mild-to-moderate vascular dementia or Alzheimer's disease with cerebrovascular disease
- Participants taking medications for the treatment of dementia, the dose must be stable for at least 6 months
- Participants who are willing to take the trial medicine every day for 12 months
- Participants and their carer(s) who are willing to attend 8 clinic visits over a 65 week period at one of our trial sites in Sydney, Wollongong, Lismore, Canberra, Brisbane, Melbourne or Adelaide



INTERESTED IN PARTICIPATING?

For further information please phone
the trial hotline on (02) 4620 3578 or email
dementiatrial@westernsydney.edu.au

nicm.edu.au

p. +61 2 9685 4700
e. nicm@westernsydney.edu.au
a. Locked Bag 1797 Penrith NSW 2751 Australia

WESTERN SYDNEY
UNIVERSITY

