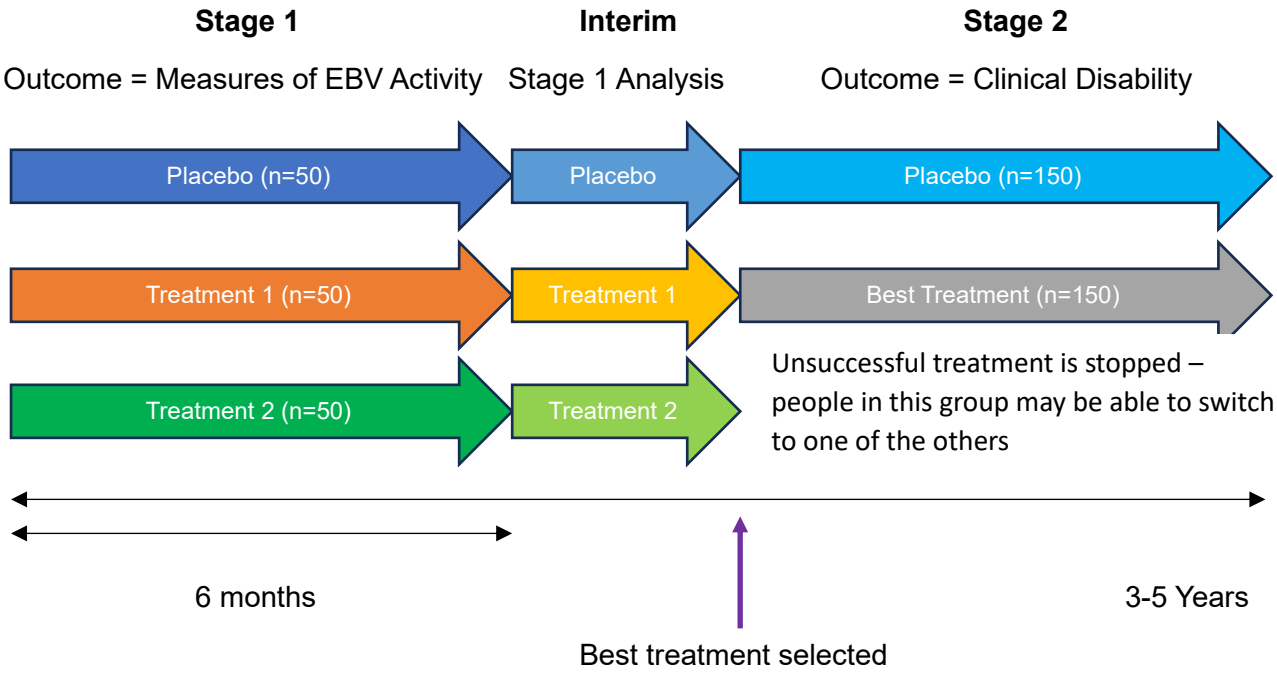
STOP–MS - Patient Information Summary

Study Purpose and Design

Epstein Barr Virus (EBV) is a contributing factor to the onset of Multiple Sclerosis (MS) and may contribute to the ongoing progression of MS. The STOP-MS trial aims to test 2 potential anti-EBV therapies. In the first stage we will assess the effectiveness of the 2 therapies to remove or lower EBV activity in 150 participants (50 people will be in each group as below). For Stage 2 the most effective of the two therapies tested from Stage 1 will be selected and tested against placebo for clinical effectiveness in MS outcomes in 300 participants (150 in each group).

Study Design



Eligibility criteria

Age 25 -70 years

Progressive MS (Primary or Secondary)

Some degree of disability

Evidence of progression over two years

Study Team

Academic neurologists, scientists, statisticians and people with MS from across Australia led by Professor Simon Broadley at Griffith University.

Voluntary Participation

Your involvement is entirely voluntary.

Study Requirements

You will be required to attend study visits, answer questionnaires, have an ECG and undergo blood tests and saliva collections at regular intervals as indicated below. If enrolled you will be asked to take medication twice per day for the duration of the study (maximum 5 years). Total time commitment is approximately 29 hours compared to 8-10 hours of normal care over this period.

There are a number of research sites participating across Australia.

Schedule of Events

Year	1													2				3			
Weeks	-4	0	1	3	4	6	8	12	16	20	24	36	48	60	72	84	96	108	120	132	144
Clinic Visit	●	●			●						●		●		●		●		●		●
PROM		●											●				●				●
ECG	●																				
Bloods	●		●	●		●		●			●	●	●	●	●	●	●	●	●	●	●
Saliva	●	●			●		●	●	●	●	●										
MRI	●												●				●				●

PROM = patient reported outcome measure (questionnaires)

Optional Studies

Genetic “fingerprint” testing

Blood biomarker testing

Potential future testing on stored samples

You can opt in or out of these components. These studies aim to understand why a particular treatment did or did not work.

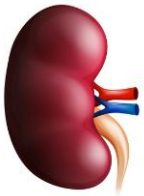
Risks

Both treatments are currently approved medications for use in Australia by the Therapeutic Goods Administration for conditions other than MS. They are generally considered to be safe but there are potential risks (shown below).

1. High potassium levels and cardiac arrhythmias can occur

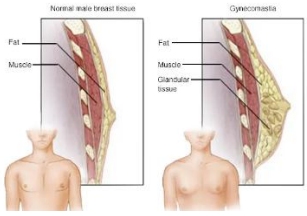
(This will be monitored for)

2. Kidney failure (can worsen side effects of the treatments)



(This will be monitored for)

3. Gynaecomastia in men (may occur in 1 in 10 men)



4. Pregnancy and Breast Feeding – treatments could be harmful to the baby

(Women of childbearing potential are required to use contraception)

5. Urinary incontinence may be worsened

6. Other potential side effects

Headache

Dizziness

Gastrointestinal upset

Rash

Drowsiness

Rash

Abnormal liver tests

Confusion

Confidentiality

Your personal information will always be treated as confidential and only disclosed to third parties where this is required for regulatory purposes (e.g. external monitoring of the trial).

Withdrawal

You are free to withdraw from the STOP-MS trial at any time for any reason. Your decision to withdraw will in no way affect your future care.

Who is Funding the STOP-MS Trial

The STOP-MS trial is being funded a competitive grant from the Medical Research Future Fund administered by the National Health and Medical Research Council of Australia (Federal Government). This grant was awarded to Griffith University who are the Sponsor for the trial.

Ethical Approval for STOP-MS Trial

This trial has been approved by the Gold Coast Hospital and Health Service Human Research Ethics Committee (HREC) – Reference: HREC/2023/QGC/101052

HREC Contact Details

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