

Safety and efficacy of intranasal delivery of BromAc® (Bromelain & Acetylcysteine) in swab positive SARS-CoV-2 COVID-19 patients

ACTRN12620000788976

Status	RECRUITING
Phase	Phase 1
Sponsor	Mucpharm Pty Ltd
Enrollment	40 participants

Plain Language Summary

This study is testing a nasal spray treatment called BromAc — a combination of two natural enzymes, Bromelain (from pineapple) and Acetylcysteine — as an early treatment for people who have tested positive for COVID-19. The idea is that BromAc can break down the spike protein on the outside of the COVID-19 virus, potentially making it non-infectious and stopping it from spreading deeper into the lungs. The nose is believed to be the primary entry point for the virus, making nasal treatment a promising early intervention.

This is a Phase 1 safety trial for adults who have recently received a positive COVID-19 PCR swab result, are experiencing mild symptoms, and are well enough to stay at home in isolation. The treatment is delivered as a nasal spray, and participants will be monitored through repeat PCR testing to see if the viral load decreases.

You may be eligible if you are 18 or older, have a confirmed positive COVID-19 swab within the last 3 days, are only mildly unwell and not requiring hospital care, and live within 50 km of a study site. You would not be eligible if you have a known allergy to pineapple, papain, or Acetylcysteine, or if you are taking blood-thinning medications.

Key Eligibility Criteria

Inclusion (7)

- Aged 18 years or older
- Swab positive for SARS-CoV-2 based on RT-PCR (patients must be identified and commence treatment within 3 days of the positive result)
- Diagnostic PCR or pre-treatment PCR must have viral load titre measurement
- Swabbed within 48 hours of symptom onset
- Remain generally well and as an outpatient in isolation in their home

... and 2 more (see full listing online)

Exclusion (10)

- Have symptoms from SARS-CoV-2 that warrant admission to hospital, require supplemental oxygen therapy or are an inpatient in a hospital for SARS-CoV-2
- Are unwilling to undergo repeat swab for PCR viral load
- On anti-viral therapy for SARS-CoV-2 (for e.g. Remdesivir, Interferon-beta1alpha) or are enrolled in another clinical trial for SARS-CoV-2
- Have known allergy (anaphylaxis) to pineapples, papain, bromeliads, sulphur, eggs or Acetylcysteine that cannot be managed with steroids or antihistamine prophylaxis or any other serious unrelated allergy
- Have a coagulation disorder of any kind or are on anticoagulant or anti-platelet therapy that cannot be withheld for the treatment period

... and 5 more (see full listing online)

Locations (1 total)

<https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12620000788976>

Royal Melbourne Hospital - Royal Park campus - Parkville, VIC, Australia

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