Positioning of Esketamine Treatment (PoET) Study

Referral Form

Esketamine is a new derivative of Ketamine, a well-known anesthetic. Esketamine has gained attention for its potential as a novel treatment for depression, particularly in individuals who have not achieved an adequate response with antidepressants.

The research team at CADE clinic, Royal North Shore Hospital is looking for participants to enroll in our "Positioning of Esketamine Treatment (POET) in the real-world management of Depression" study.

The aims for this study are 1) to examine the positioning of Esketamine in real-world clinical practice and 2) to identify patient and illness characteristics that respond well to Esketamine.

Below is a list of **inclusion** and **exclusion** criteria:

Inclusion Criteria

To be eligible, participants must:

- Be an adult aged 18-65 years old
- Have a **primary diagnosis** of Major Depressive Disorder (MDD)
  ****Please note: a co-morbid diagnosis of an anxiety disorder or ADHD can be included****
- Be currently depressed and on medication for current episode
- Have experienced an inadequate response[1] to 2 or more courses of antidepressants (of adequate dose and duration)
- Be able to understand and provide informed consent

If enrolled in the study, participants will be maintained on their current antidepressant medication or psychological therapy, with the addition of Esketamine, administered via nasal spray.

Exclusion Criteria

Participants are **excluded** if they have:

1. Concurrent diagnoses
   - Participants with DSM-5 disorders e.g., current substance misuse disorders, bipolar disorder, schizophrenia.
   - Participants who are unable to understand the study and therefore unable to provide informed consent.
2. Pregnancy
   - Participants who are pregnant and/or breastfeeding.
   - Participants who are not willing to avoid pregnancy for themselves or their partners during the study by using effective birth control methods.
3. Current medications
   - Participants taking:
     - A total daily dose of benzodiazepines greater than the equivalent of 6mg/day of lorazepam.
     - Complementary and alternative medicine therapies e.g., St John's wort, Chinese medicines, and various herbal and homeopathic treatments.

[1] Inadequate response is assessed using clinical judgement

4. Stimulants
    - Participants taking stimulants such as methylphenidate, amphetamine, and dextroamphetamine for a diagnosis such as ADHD can still have Esketamine provided they do not continue taking stimulants concurrently for the duration of the study.
    - Concurrent use is excluded due to the synergistic effect with Esketamine that can cause increased blood pressure.
5. Medical history
    - Participants with the following illnesses:
        - Current or past history of seizures (uncomplicated childhood febrile seizures with no sequelae are not exclusionary).
        - A history of uncontrolled hypertension.
        - Uncontrolled diabetes mellitus.
        - Aneurysmal vascular disease including thoracic and abdominal aorta, intracranial and peripheral arterial vessels, or arteriovenous malformation, intracerebral haemorrhage.
        - Untreated glaucoma, current penetrating or perforating eye injury, brain injury, hypertensive encephalopathy, intrathecal therapy with ventricular shunts, or any other condition associated with increased intracranial pressure or increased intraocular pressure or planned eye surgery.
    - Participants currently receiving Electroconvulsive Therapy (ECT) or have received ECT in the past month
6. Substance Misuse History
    - Participants who have ever had a substance misuse disorder involving any of the following over their lifetime:
        - Ketamine, phencyclidine (PCP), lysergic acid diethylamide (LSD), or 3,4-methylenedioxy-methamhetamine (MDMA), or other hallucinogens.
    - Participants with hypersensitivity to Esketamine, Ketamine, or any of the excipients in these formulations.

Eligibility to participate in the study is dependent on the assessments conducted by the study team. If you have any questions about the inclusion/exclusion criteria for your patient, please contact the trial coordinator at NSLHD-researchpoet@health.nsw.gov.au

If you think your patient may be eligible to participate in the study, please complete and return the referral form below. The study team will contact the patient to arrange a screening. If your patient is enrolled in the study, we will keep you informed of their commencement, progress, completion of treatment and if they dropout.

Instructions

1. Complete the below Referral Form on page 3 & 4
2. Email completed Referral Form and supporting documentation to: nslhd-researchpoet@health.nsw.gov.au
3. Once the referral and supporting documentation is received, the patient will be contacted and our team will work with the patient to arrange a time and day for assessment.

Failure to provide sufficient details in this referral form will prevent the clinic from being able to assess the suitability of your patient. This will result in the clinic being unable to offer an appointment.

Request

Date:

Health Practitioner Details (referring physician)		
First Name:	**Surname:**	**Provider No:**
Position:		
Health Service/Practice Name:		
Address:	**State:**	**Postcode:**
Phone:	**Email:**	
Treating Psychiatrist:		
Preferred Contact: ☐ **Phone** ☐ **Email**		

General Practitioner Details (if the referring physician is NOT the patient's GP, please provide the patient's GP details below)		
First Name:	**Surname:**	**Provider No:**
Position:		
Health Service/Practice Name:		
Address:	**State:**	**Postcode:**
Phone:	**Email:**	

Patient Details		
First Name:	**Surname:**	**DOB:**
Medicare No:		**Ref No:**
Address:	**State:**	**Postcode:**
Phone:	**Email:**	
Sex:		
Preferred Contact: ☐ **Phone** ☐ **Email**		

Clinical Notes

Please include the following details **(attach additional pages and documents if necessary)**

Patient's Most Recent Blood Pressure Values
(Please provide **TWO** most recent values and dates they were obtained)
History of Mood Disorder
(Age of onset, number of episodes (if known), pattern of episodes, periods of euthymia)

Current and Past Treatment History
(All trials of psychological, pharmacological and physical treatments, including any blood pressure medication)
Describe Patient's Eligibility to Enrol in Esketamine Study
(Please ensure patient is not on the exclusion criteria list)