NP202-002

NCT02557217

Principal Investigator: Dr. Safwan Kassas, MD (Covenant)

Condition: ST Elevation Myocardial Infarction

Drug: NP202 vs. Placebo

Official Title: A Phase II Randomised, Double-Blind, Placebo-Controlled Study of the Efficacy, Safety and Tolerability of Oral NP202 in Adults Who Have Left Ventricular Systolic Dysfunction Following Myocardial Infarction

Sponsor: Armaron Bio Pty Ltd

Purpose: NP202 is an experimental drug being developed by Armaron Bio Pty Ltd for potential use as a treatment for people after they have had a heart attack (MI).

Inclusion Criteria:

- Have had a confirmed ST elevation myocardial infarction (STEMI) in the previous 5 days, which met all of the following criteria:
  - ≥ 0.2mV ST elevation in 2 or more V1 - V6 leads with presentation in a maximum of 12 hours of onset of symptoms
  - Troponin levels >10 x upper limit of normal (ULN) at the site's local laboratory.
  - Successful revascularization by Percutaneous Coronary Intervention (PCI)
- Have left ventricular dysfunction post STEMI as evidenced by left ventricular ejection fraction (LVEF) ≤40% confirmed by echocardiogram at screening.
- Are receiving guideline-directed medical therapy for acute MI and post-MI left ventricular (LV) dysfunction according to national cardiology society/heart association STEMI guidelines.

Exclusion Criteria:

- Known cardiomyopathy or heart failure prior to MI.
- Cardiogenic shock and/or systolic blood pressure <85mmHg at Screening.
- Clinical history of ejection fraction ≤40% prior to this MI, or multiple prior MIs.
- Daily use of non-steroidal anti-inflammatory drugs (NSAIDs) and/or cyclooxygenase-2 (COX-2) inhibitors in the past month.
- Presence of device/hardware incompatible with MRI
- Estimated glomerular filtration rate (eGFR) <30ml/min
- Liver function tests 3 x ULN due to non-cardiac disease
- Have received any investigational research agent within 30 days or 5 half-lives (whichever is longer) prior to the first dose of investigational product.

Source: https://clinicaltrials.gov/ct2/show/NCT02557217
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