

Investigation of AV411 in neuropathic pain

ACTRN12606000403538

Status	RECRUITING
Phase	Phase 2
Sponsor	Avigen, Inc.
Enrollment	36 participants

Plain Language Summary

This study is testing a new drug called AV411 (ibudilast) to see if it can reduce pain in people with nerve pain (neuropathic pain). Nerve pain is a burning, shooting, or electric-shock-like pain caused by damage to the nerves, and it can be very difficult to treat. This study focuses on people with either diabetic neuropathy (nerve damage from diabetes) or complex regional pain syndrome (CRPS). AV411 works differently from most pain medications — it targets brain immune cells rather than nerve signals — which may make it effective for conditions where standard treatments do not work well.

You may be eligible if:

- You are between 18 and 70 years old
- You have been diagnosed with diabetic neuropathy or complex regional pain syndrome for at least 6 months
- Your pain score is 4 or higher on a 10-point scale
- You have been on stable pain medications for at least 8 weeks
- You are willing to use barrier contraception during the study
- Female participants of childbearing potential must have a negative pregnancy test

You may NOT be eligible if:

- You have untreated mental illness, drug addiction, or alcohol abuse
- You have donated blood in the past 90 days
- You have a low platelet count or a history of bleeding problems
- You have chronic liver disease
- You have reduced kidney function (GFR 90 mL/min/1.73m² or less)
- You are pregnant or breastfeeding
- You have taken another investigational drug in the past 90 days

Talk to your doctor about whether this trial might be right for you.

Key Eligibility Criteria

Inclusion (1)

- Diagnosis of diabetic neuropathy or complex regional pain syndrome of at least 6 months duration.-VAS score of 4 cm or higher at screening.-No clinical abnormality in laboratory and urine analyses.-Electrocardiogram within normal limits at screening.-Negative pregnancy test on Study Day 1 for female subjects of childbearing potential.-On stable doses of medications, analgesic or others for at least 8 weeks prior to study enrollment.-Willing to use barrier contraceptive during the period of the study.

Exclusion (1)

- Known hypersensitivity to AV411 or its components.-Conditions which might affect drug absorption, metabolism or excretion.-Untreated mental illness, current drug addiction or abuse or alcoholism.-Donated blood in the past 90 days or have poor peripheral venous access.-Platelets <100,000 mm³ or a history of thrombocytopenia.-Known or suspected chronic liver disease.-GFR ≤ 90 mL/min/1.73m² (Cockcroft-Gault).-Female subjects who are pregnant or nursing mothers.-Received an investigational drug in the past 90 days.-Unable to swallow large capsules.

<https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12606000403538>

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Locations (1 total)

Australia

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