

# Resiniferatoxin to Treat Severe Pain Associated With Advanced Cancer

NCT00804154

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<b>Status</b>	RECRUITING
<b>Phase</b>	Phase 1
<b>Sponsor</b>	National Institute of Dental and Craniofacial Research (NIDCR)
<b>Enrollment</b>	45 participants

## Key Eligibility Criteria

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### Inclusion (31)

- Age 18 years or older.
- Clinical and histological diagnosis of cancer with disease that has not adequately responded to standard therapies. A pathology report documenting malignancy is required.
- Subject not currently seeking or receiving potentially curative therapies for cancer (e.g., chemotherapy or immunotherapy). Curative cancer therapy may be sought after the Day 15 clinic visit, and palliative anti-tumor therapy is allowed as long as the subject was established on that therapy prior to enrollment (see exclusion criterion 6).
- Mean daily worst pain NRS score of greater than or equal to 6 for pain at or below the T6 dermatome (level of the chest) that is associated with a malignant disease. The mean score must be derived from recordings on at least 4 of 7 consecutive days within 3 weeks preceding treatment.
- Alternative methods of pain control are not sufficiently effective, not indicated, not tolerated, and/or refused by the subject, as determined by the Pain and Palliative Care Service (PPCS). Alternative methods of pain control include, but are not limited to, the following:

... and 26 more (see full listing online)

### Exclusion (20)

- Subjects will be excluded from the study if they meet any of the following criteria:
- Primary pain source from anatomical regions at T5 dermatome or above.
- Pain due to causes other than cancer or its treatment that is moderate to severe in intensity.
- Anatomic abnormality or pathology of the spinal cord and/or IT space on magnetic resonance imaging (MRI) that could increase the risk of adverse effects of catheter placement or interfere with CSF flow.
- Evidence of advanced brain pathology or elevated intracranial pressure as determined by symptoms, history, physical examination (including neurological and eye examination), and/or MRI.

... and 15 more (see full listing online)

## Locations (1 total)

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National Institutes of Health Clinical Center, Bethesda, Maryland, United States

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<https://clinicaltrials.gov/study/NCT00804154>

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