

# Evaluation of the Response and Non-response of Nirogacestat in Desmoid Tumors- Clinical Study

NCT05879146

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Status	RECRUITING
Phase	Phase 2
Sponsor	M.D. Anderson Cancer Center
Enrollment	40 participants

## Key Eligibility Criteria

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### Inclusion (26)

- This study will enroll approximately 40 participants diagnosed with DT. Participants must meet the following eligibility criteria to be enrolled:
- Age  $\geq$  18 years. Individuals younger than 18 years old are excluded. More than 99% of the population evaluated at MDACC with a diagnosis of DT is older than 18. Sixty-three percent of the population with a diagnosis of DT evaluated at MDACC are 10 - 54 years old. The remaining 37 percent are older than 54 years old. Additionally, most of the robust data related to dosing or adverse event data currently available on the use of nirogacestat is in adults
- Histologically documented DT with evidence of radiographic tumor progression ( $\geq$  10% or absolute increase in dimensions of  $\geq$  10 mm in maximal diameter) in unidimensional measurement within the previous 18 months. Patients must have measurable disease, defined as at least one lesion that can be accurately measured in at least one dimension as  $\geq$  10 mm ( $\geq$  1 cm) with CT scan, MRI, or calipers by clinical exam
- Recurrent or primary disease
- Symptomatic disease or impending morbidity (as defined by physician) and patient and physician agree treatment would be of benefit

... and 21 more (see full listing online)

### Exclusion (18)

- Participants are excluded from this study if any of the following criteria apply:
- Unable to undergo serial biopsies
- Participants with familial adenomatous polyposis
- Unable to tolerate MRI or for whom MRI is contraindicated
- Pregnant or breastfeeding women are excluded from this study. Based on findings in animal studies, oral administration of nirogacestat to pregnant rats during the period of organogenesis resulted in embryo-fetal toxicities at maternal exposures that were significantly lower than adult human exposures at the recommended dose of 150 mg twice daily. Nirogacestat should be avoided during pregnancy

... and 13 more (see full listing online)

## Locations (1 total)

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M D Anderson Cancer Center, Houston, Texas, United States

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<https://clinicaltrials.gov/study/NCT05879146>

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