

Psilocybin in Cancer Pain Study

NCT06001749

Status	RECRUITING
Phase	Phase 2
Sponsor	Yvan Beaussant, MD, MSci
Enrollment	15 participants

Key Eligibility Criteria

Inclusion (19)

- Participants must be 18 year old or older;
- Participants must have advanced cancer, defined as a cancer that is unlikely to be cured or controlled with treatment;
- Participants must have progressed on or be intolerant to approved therapies with a known clinical benefit (unless it is documented that they have refused such treatments);
- Participants must evaluate their average pain on BPI Severity Scale e 4/10 over the past week;
- Participants must receive chronic opioid pharmacotherapy for pain with an Oral Morphine Equivalent (OME) e 200mg/day;
- ... and 14 more (see full listing online)

Exclusion (31)

- Participants who receive concurrent (less than four weeks or planned within 6 weeks) cytotoxic chemotherapy or radiation therapy that may impair general level of physical functioning or affect study outcomes;
- Participants with a condition impairing oral intake or digestive absorption;
- Participants who are not able to give adequate informed consent;
- Participants who have a significant suicide risk as defined by suicidal ideation with intent and with or without a plan as endorsed on items 4 and/or 5 on the C-SSRS within the past 6 months or at V0
- Participants who have a history of, or a current diagnostic of primary psychotic disorder, major depressive disorder with psychotic features, bipolar affective disorder type 1 or history of or current dissociative identity disorder; and participants who have an ongoing substance use disorder (defined as active in the past year). Participants with first-degree relatives with schizophrenia or bipolar disorder may be eligible depending on their age and personal and family psychiatric history. The decision will be made by the principal investigator and study psychiatrist based on risk assessment.
- ... and 26 more (see full listing online)

Locations (1 total)

Dana-Farber Cancer Institute, Boston, Massachusetts, United States

<https://clinicaltrials.gov/study/NCT06001749>

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