

Pilot Study

Lucentra ONCO™ in Patients With Symptoms Associated With Cancer and the Treatment of Cancer

A Prospective Pilot Study Evaluating the Feasibility, Tolerability, and Patient-Reported Symptom Changes Associated With Lucentra ONCO in Adults With Cancer Undergoing Systemic Therapy

1. Background and Rationale

Patients receiving cancer treatment commonly experience fatigue, nausea, neuropathy, anxiety, insomnia, cognitive impairment, and digestive discomfort. These symptoms often occur in clusters and can substantially impair quality of life, adherence, and daily functioning. Integrative oncology programs increasingly explore complementary interventions to address these burdens. The article set you uploaded includes experimental cancer-model work, systematic reviews in oncology, observational homeopathy studies, and integrative oncology practice literature, which together support a pilot feasibility study in this area.

Research Articles for Lucentra

Lucentra ONCO is an alcohol-free liquid homeopathic formulation intended to support symptoms associated with cancer and the treatment of cancer. Because current evidence is preliminary and heterogeneous, an initial **prospective pilot study** is the appropriate next step before any larger controlled trial.

2. Study Objectives

Primary Objective

To evaluate the **feasibility and tolerability** of Lucentra ONCO in adults undergoing treatment for cancer.

Secondary Objectives

To assess preliminary changes in patient-reported:

- fatigue
- nausea

- neuropathy
- anxiety
- insomnia
- cognitive symptoms / brain fog
- overall quality of life

Exploratory Objective

To identify which symptom clusters appear most responsive and to estimate effect sizes for a later randomized study.

3. Study Design

Design Type

Prospective, single-arm, open-label pilot study

Duration

28 days per participant

Setting

Integrative oncology clinic, supportive care clinic, or community oncology practice with complementary medicine oversight.

Sample Size

20 to 30 participants

This size is appropriate for a pilot focused on:

- feasibility
 - protocol adherence
 - tolerability
 - signal detection for symptom change
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4. Study Population

Inclusion Criteria

Participants must meet all of the following:

- age 18 years or older
- confirmed diagnosis of solid tumor or hematologic malignancy
- currently receiving active cancer treatment, such as chemotherapy, immunotherapy, endocrine therapy, or targeted therapy
- experiencing at least **2 moderate symptoms** from the following list:
 - fatigue
 - nausea
 - neuropathy
 - anxiety
 - insomnia
 - cognitive impairment / brain fog
 - digestive discomfort
- able to provide informed consent
- willing to continue standard oncology care throughout the study

Exclusion Criteria

- inability to complete study questionnaires
 - anticipated hospitalization during the observation period
 - uncontrolled psychiatric or neurologic illness that would confound symptom assessment
 - participation in another symptom-intervention trial likely to interfere with outcomes
 - known allergy or intolerance to glycerin-based oral drops
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5. Intervention

Study Product

Lucentra ONCO liquid formulation

Proposed Dosing

10 drops orally twice daily

May be taken:

- directly under the tongue, or
- diluted in a small amount of water

Treatment Duration

28 consecutive days

Concomitant Care

Participants will continue:

- chemotherapy
- antiemetics
- analgesics
- neuropathy medications
- sleep medications
- other prescribed treatments

No conventional care will be withheld.

6. Study Endpoints

Primary Endpoints

1. Feasibility

- enrollment rate
- retention rate
- dosing adherence
- completeness of symptom diaries

2. Tolerability

- adverse events
- discontinuations due to intolerance

Secondary Endpoints

Change from baseline to Day 7, Day 14, and Day 28 in:

- fatigue score
- nausea score
- neuropathy score
- anxiety score
- insomnia score
- cognitive symptom score
- global symptom burden
- overall quality-of-life score

Exploratory Endpoints

- use of rescue medications for nausea, sleep, or pain
 - patient global impression of change
 - clinician global impression of change
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7. Outcome Measures

Recommended Instruments

Symptom Severity

Use **0-10 Numeric Rating Scales** for each symptom:

- fatigue
- nausea
- neuropathy
- anxiety
- insomnia
- brain fog / memory problems
- digestive discomfort

- pain

Quality of Life

Use one standardized instrument, such as:

- **ESAS-r** (Edmonton Symptom Assessment System Revised), or
- **FACT-G** (Functional Assessment of Cancer Therapy – General)

Patient Global Impression

PGIC:

“Compared with when you started Lucentra ONCO, how are your symptoms now?”

8. Study Procedures

Baseline Visit (Day 0)

Collect:

- demographics
- cancer diagnosis and stage
- current treatment regimen
- concomitant medications
- baseline symptom scores
- quality-of-life questionnaire

Dispense Lucentra ONCO and dosing instructions.

Follow-Up Assessments

Day 3 or 4

Phone or telehealth check:

- adherence
- early tolerability
- immediate symptom changes

Day 7

Collect symptom scores and patient impression of change.

Day 14

Repeat symptom scores, adherence review, adverse event review.

Day 28

Final assessment:

- symptom scores
 - quality of life
 - tolerability
 - overall patient satisfaction
 - investigator assessment
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9. Statistical Plan

Because this is a pilot study, the emphasis is on estimation rather than hypothesis confirmation.

Analyses

- descriptive statistics for baseline characteristics
- mean change from baseline at Days 7, 14, and 28
- within-subject comparisons using paired tests
- effect size estimates for each symptom domain
- responder analysis, such as:
 - at least 2-point reduction on 0-10 scale
 - at least 30 percent improvement from baseline

Feasibility Benchmarks

The pilot will be considered feasible if:

- at least 70 percent of eligible patients enroll
- at least 80 percent complete Day 28

- at least 75 percent maintain dosing adherence
 - no major tolerability concerns emerge
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10. Safety Monitoring

Lucentra ONCO is intended as a complementary supportive product. Even in a low-risk pilot, all adverse events should be documented.

Safety Procedures

- record all adverse events at each contact
- classify severity and relationship to study product
- immediate clinician review for unexpected events
- participants remain under standard oncology supervision

Stopping Considerations

Pause or review the study if:

- unexpected serious adverse events occur
 - multiple participants discontinue due to intolerance
 - clinicians identify interference with standard care
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11. Ethical Positioning

This study should clearly state:

- Lucentra ONCO is **not a substitute for cancer treatment**
- all participants continue conventional oncology care
- the study evaluates supportive symptom management only

Suggested statement for protocol:

Lucentra ONCO is being evaluated as a complementary supportive intervention for patient-reported symptoms associated with cancer and the treatment of cancer, alongside standard medical care.

12. Expected Deliverables From the Pilot

This pilot can generate:

- feasibility data for grant or investor discussions
 - a manuscript suitable for an integrative oncology journal
 - preliminary effect-size estimates
 - practical dosing and adherence information
 - refined inclusion criteria for a randomized study
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13. Suggested Next-Step Trial After the Pilot

If the pilot is successful, the logical next study would be:

Phase 2 Randomized Controlled Trial

Population: patients starting taxane- or platinum-based chemotherapy

Design: Lucentra ONCO vs placebo, both with standard supportive care

Duration: 4 to 8 weeks

Primary endpoint: composite symptom burden or fatigue/nausea reduction

Secondary endpoints: neuropathy, sleep, anxiety, quality of life

Appendix A: Brief Case-Based Justification

Two preliminary observational cases support the choice of symptom domains for this pilot:

Case A

A 72-year-old man with metastatic prostate cancer receiving docetaxel and androgen suppression experienced neuropathy, impaired cognition, extreme fatigue, insomnia, anxiety, and bone pain. After Lucentra ONCO, he reported early improvement in energy and anxiety, with improvement in neuropathy and insomnia over the next week.

Case B

A 35-year-old woman with stage IV cervical cancer receiving carboplatin/paclitaxel with or without bevacizumab developed severe nausea and extreme fatigue after her first chemotherapy session. After Lucentra ONCO, she reported rapid improvement in nausea and later improvement in fatigue.

These cases do not establish causality, but they support selecting **fatigue, nausea, neuropathy, anxiety, insomnia, and cognitive symptoms** as pilot endpoints.