

# Trial to Study Anti- HCMV Therapy in Breast Cancer Patients With Progressive Intracranial Metastases and CMV Infection

NCT07383649

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<b>Status</b>	RECRUITING
<b>Phase</b>	Phase 2
<b>Sponsor</b>	The Methodist Hospital Research Institute
<b>Enrollment</b>	28 participants

## Key Eligibility Criteria

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### Inclusion (15)

- Male or female aged  $\geq 18$  years at the time of consent
- Breast cancer with progressive brain metastases supra and/or infratentorial. Patients can proceed with SRS as long as at least 1 lesion which is 2 cm or less in a noncritical area in the brain is spared as per the discretion of treating neurosurgeon/radiation oncologist.
- At least one non irradiated, untreated progressive brain metastases site
- Serum HCMV DNA by real time PCR  $\geq 250$  copies/ml or positive CMV Ig G or Ig M.
- Capable of giving signed informed consent which includes compliance with the requirements and restrictions listed in the informed consent form and in this protocol. If the patient is unable to consent for any reason a legally authorized guardian may provide consent on their behalf. Written informed consent and any locally required authorization (e.g., Health Insurance Portability and Accountability Act) will be obtained from the patient prior to performing any protocol-related procedures, including screening evaluations.

... and 10 more (see full listing online)

### Exclusion (13)

- Single resectable intracranial lesion
- Last intracranial progression free survival  $\geq 12$  months
- All progressive brain metastases have been radiated
- Brain metastases needing immediate local intervention such as mass effect, herniation, active neurological symptoms, increased intracranial pressure, those near vital structures like the motor cortex, proximity to the optic nerve/chiasm or brain stem etc (can still be included if there are any other non-radiated progressive brain metastases) Multidisciplinary discussion with neurosurgery and radiation oncology will be needed to determine which patients may be safely enrolled on the trial.
- Active pregnancy or breast feeding

... and 8 more (see full listing online)

## Locations (1 total)

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Houston Methodist Neal Cancer Center, Houston, Texas, United States

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<https://clinicaltrials.gov/study/NCT07383649>

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