

**Protocol Title:** Randomised phase II trial testing efficacy of intra-tumoural hydrogen peroxide a radiation sensitiser in patients with locally advanced/recurrent breast cancer-CCR5119 KORTUC

**Subject No:** 07/5119/029

**Date of Onset:** 29 Mar 2026

**Date of Death:** 29 Mar 2026 [Notified to IRB on 22 Apr 2026]

**CTRI Regd. No:** CTRI/2022/02/040331

**Adverse Event:** Myocardial infarction

**Causality:** Unlikely to be related to the trial intervention

**Outcome:** Death

**Severity:** Grade V

**Brief History:**

- **20-SEP-2025:**
  - Completed palliative radiotherapy (36 Gy in 6 fr) for metastatic carcinoma of the left breast.
  - Exemestane therapy initiated following documented disease progression during the post- radiotherapy surveillance period.
- **15-MAR-2026:** Transitioned to best supportive care under a palliative team due to escalating respiratory distress and a significant decline in performance status, which precluded further active oncological intervention.
- **29-MAR-2026:** The patient passed away at 06:05 AM; the immediate cause of death recorded on the death certificate by local physician > acute coronary syndrome.
- **06-APR-2026:** Trial site notified of the patient's death. The delay in reporting was due to the family not proactively informing the study team at the time of the event.

**SAE subcommittee decision:**

- **Time relationship:** Appropriate
- **Competing Causes:** Disease progression
- **De-Challenge/ Re-challenge:** NA
- **WHO-UMC Causality:** unlikely to be related to trial

**IRB Decision:** The patient had further disease progression and likely died as a result of the progressive disease. The cause of death was deemed to be ACS. No compensation is recommended.

**Financial compensation:** Not Applicable for compensation and medical management