A pathologic complete response (pCR) following neoadjuvant chemotherapy was associated with improvements in overall survival. Patients receiving neoadjuvant chemotherapy have shown positive clinical outcomes, with a pathologic complete response rate of 20-40%. This study evaluated the efficacy and safety of niraparib, a PARP inhibitor, in patients with BRCA-mutant breast cancer.

**OBJECTIVES**

- **Primary Objective:**
  - Evaluate the primary tumor response rate of niraparib in the study population.
- **Secondary Objectives:**
  - Evaluate the clinical benefit of niraparib in the study population.
  - Explore the correlation between niraparib concentration and clinical benefit.

**EXCLUSION CRITERIA**

- Prior treatment with a known PARP inhibitor
- Known evidence of distant metastasis
- Complete response or suspected deleterious BRCA1 or BRCA2 mutation
- Known or suspected single nucleotide variants or copy number variants in BRCA1 or BRCA2
- History of breast cancer within the past 2 years
- History of bilateral breast cancer
- History of previous neoadjuvant chemotherapy

**STUDY ASSESSMENTS**

- **Tumor response rate:**
  - Complete response or partial response or stable disease for at least 2 months of niraparib treatment
  - Measurement of tumor size by breast MRI

- **Exploratory Objectives:**
  - Explore molecular biomarkers related to disease biology or response to treatment
  - Explore potential biomarkers of sensitivity or resistance

**METHODS**

- **Study Design:**
  - Open-label, single-arm study evaluating the antitumor activity and safety of niraparib as neoadjuvant treatment in patients with HER2-negative, BRCA-mutant breast cancer.

- **Patient Population:**
  - Patients with operable tumors
  - BRCA-mutant breast cancer

- **Drug Administration:**
  - Patients will receive niraparib orally once daily for 2 cycles (Figure 1)

- **Efficacy Endpoints:**
  - Tumor response rate based on the change in tumor volume as measured by breast MRI (calculated as length × width × height × π/2)
  - Complete response or partial response or stable disease for at least 2 months of niraparib treatment

- **Safety Endpoints:**
  - Adverse events, laboratory tests, vital signs, physical examination

**ACKNOWLEDGEMENTS**

This study (ClinicalTrials.gov, NCT03339367) is currently enrolling patients. Study is being conducted in 11 institutions (Table 1).

**REFERENCES**