Object: EUDRACT 2012-004956-12 (HOPE Trial) _ prematurely ended trial

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The primary objective of the HOPE study was to evaluate the antitumor activity of eribulin combined with an anthracycline/taxane-based regimen given as primary systemic therapy and assessed as pathological complete response rate, defined as the absence of invasive cancer in both the breast and axillary lymph nodes.
A Simons's optimal two-stage design was applied. The sample size was estimated based on expected values of pCR of 40% under the alternative hypothesis and 20% under the null hypothesis. With a type I error of 0.05 and a statistical power of 80%, 13 patients were planned in the first stage. In case of 3 pCRs or fewer in this first stage, the accrual would be stopped. If 4 or more pCRs were observed, accrual would continue to include 43 patients overall.
Between August 23, 2013 and March 9, 2015, a total of 13 patients met eligibility criteria and were enrolled in the study. The median age was 43 (range 35–75) years. At diagnosis tumor size was 2–5 cm (cT2) in 9/13 (69%), and > 5 cm (cT3) in 4/13 (30%) patients, with a median value of 4.0 (2.2–7.5) cm; clinical nodal status was positive (cN1-3) in 8/13 (61%) cases. No case of stage I was enrolled.
Pathological findings were available for all patients. Three out of 13 (23%) patients achieved a less than 1 cm residual disease. Complete absence of invasive cancer in breast and axillary nodes, ie pCR as per protocol definition, was reported in 3/13 (23%) patients. Hence, according to study design, accrual was stopped.
Complete data of HOPE study have been published in PLoS One. 2019; 14(8): e0220644. doi: 10.1371/journal.pone.0220644

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