

## A Randomized Controlled Trial to assess the role of Curcumin in patients receiving neo-adjuvant chemotherapy for breast cancer

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Curcumin is a natural yellow-pigmented polyphenol component of the spice turmeric, which is derived from the roots of the plant *Curcuma longa* plant, indigenous to Southeast Asia. The coloring & flavoring properties of Curcumin (difeuloy l methane) have led to its wide use as a dietary additive in a variety of foods. Extracts containing Curcumin have also been used in traditional Indian medicines for generations & have been useful in treatment of inflammation, skin wounds, cough, coryza & certain tumors. Curcuminoids inhibit the generation & propagation of free radicals and act as an antioxidant, inhibiting lipid peroxidation and oxidative DNA damage. The anti-inflammatory property of Curcuminoids have been attributed to the inhibition of lipo-oxygenase and cyclooxygenase resulting in decreased arachidonic acid release and metabolism, along with the property to inhibit activation of NF- $\kappa$ B. The role of Curcumin has been studied extensively in breast cancer lines, where it has been able to induce cell cycle arrest & apoptosis by inhibiting cyclin-dependent kinase (cdk) activity, suppressing cyclin D1 and cyclin E expression, increasing levels of cdk inhibitors p21 and p27, and inducing p53 transcriptional activity. Majority of Curcumin's effects have been attributed to its ability to inhibit transcriptional activity of nuclear factor kappa B (NF- $\kappa$ B), leading to reduced expression of anti-

apoptotic, proliferative, pro-angiogenic, and metastatic target genes of NF- $\kappa$ B, with subsequent inhibition of mammary tumorigenesis and metastasis in vivo. Importantly, apoptosis in response to Curcumin appears to be far more pronounced in cancer cell lines versus non-tumorigenic breast epithelial cells. With this background a prospective randomized control trial is being contemplated to assess the role of Curcumin in altering the response to NACT in patients with locally advanced breast carcinoma.

### Materials & Methods

A prospective randomized control trial is being contemplated at the Department of Surgery, Vardhman Mahavir Medical College & Safdarjung Hospital, to assess the role of Curcumin in altering the response to anthracycline based neo-adjuvant chemotherapy (NACT) in patients of locally advanced breast carcinoma (LABC). 100 histo-pathologically proven LABC patients would be included in the study after informed consent & would be randomized into two groups based on random numbers. The study group would receive oral supplementation of Curcumin along with NACT (CAF regime), whereas the control group would receive a placebo along with the NACT regime. The response to NACT would be evaluated by RECIST (Response Evaluation Criteria in Solid Tumors) criteria, after three cycles of NACT using an MRI. Statistical analysis would be carried out using the SPSS software.