

Summary of VISION- Trial (Swiss-Austrian Multicenter Study)

Neoadjuvant chemotherapy (NAC) has become common practice in the primary treatment of breast cancer. Its effect is equivocal to adjuvant chemotherapy and can therefore be used in all patients with an indication for postoperative chemotherapy. Patients with large tumors and tumors with a poor prognosis such as HER2-positive and triple negative breast cancers are most appropriate candidates for NAC. The main advantage of NAC are two fold:

- NAC gives the clinician the opportunity to assess response to a given preoperative regimen in vivo; via imaging during NAC and of course by studying residual cancer in pathology tissue specimens taken at surgery.
- NAC also enables a de-escalation from mastectomy to breast conserving procedures in cases with large tumors. Furthermore, NAC can prevent fully axillary dissection if lymph node response upon imaging is favorable.

The use of modern NAC regimens leads to a pCR of the tumor in more than 50% of cases. In these cases open surgery serves only to prove full remission- indeed it could be argued that these invasive procedures could be de-escalated to interventional biopsies. According to the current literature, pCR is most accurately predicted using MRI. Nevertheless, imaging cannot predict pCR with sufficient accuracy. Therefore, following NAC, breast conserving surgery or mastectomy is conducted in accordance with clinical indications.

The main objective of this multicenter interventional cohort is the calculation of sensitivity, specificity, negative predictive value and positive predictive value for the post-NAC vacuum assisted biopsy (VAB) in determining pCR compared to conventional surgical resection.

In patients scheduled for operation after NAC and MRI indicating complete response, eight vacuum-assisted biopsies will be taken in the tumor bed using a 7-gauge EnCor needle under general anesthesia just prior to surgical intervention. Alternatively, this procedure can be done before surgery in the framework of localizing the wire to the tumor bed. These biopsies will be taken in close proximity to the Hydromark®-Clip. Subsequently, conventional surgery will be performed. If indicated, surgeons may perform axillary surgery. Results for both tissue samples will be compared to determine whether VAB in cases where MRI indicates complete response can reliably predict pCR in patients who have undergone NAC.

This trial aims to study interventional biopsy in combination with MRI in comparison to classic open surgery. Our results may lead to a de-escalation of therapy in women with excellent recent response to NAC and open up broad studies of interventional image guided procedures of the breast.

Principal Investigator
PD Dr. med. Christoph Tausch
Brust-Zentrum Zürich
c.tausch@brust-zentrum.ch