NordicTrip
NORDIC BREAST GROUP

Consent, Inclusion 1(2)

Study number:

Year of birth:

Study site:

Inclusion criteria, all should be recorded with "Yes":

Signed Informed consent	☐ No	☐ Yes
Age ≥ 18 - <76 years	☐ No	☐ Yes
Histologically confirmed unilateral adenocarcinoma of the breast where neoadjuvant chemotherapy followed by definitive surgery is planned	☐ No	☐ Yes
Node-positive disease (N1-3) or if N0 Tumour size ≥ 20 mm When deciding T-stage the following hierarchy applies, a. MRI b. Ultrasound c. Mammography d. Clinical examination	☐ No	☐ Yes
ER negative disease, defined by at least **one** of the following: a. ER < 1% cells positive by immunohisochemistry (IHC) or ER ≤10% cells positive by IHC and basal-like subtype using gene expression analysis b. ER ≤ 10% cells positive by IHC and PgR ≤ 10% cells positive by IHC	☐ No	☐ Yes
HER2-normal tumor defined according to applicable national guidelines	☐ No	☐ Yes
Consent for germline mutation screening for BRCA1, BRCA2 and other inherited breast cancer associated genes	☐ No	☐ Yes
WHO performance status 0 or 1	☐ No	☐ Yes
Negative pregnancy test in women of childbearing potential (premenopausal or <12 months of amenorrhea post-menopause and who have not undergone surgical sterilization)	☐ No	☐ Yes
Willingness of female patients of childbearing potential, and male patients and their sexual partners to use an effective means of contraception during the treatment period and at least 6 months thereafter	☐ No	☐ Yes
Willingness by the patient to undergo treatment and study related Procedures according to the protocol	☐ No	☐ Yes

Exclusion criteria, all should be recorded with "No":

Clinical or radiological signs of metastatic disease	☐ No	☐ Yes
History of other malignancy within the last 5 years, except for carcinoma in situ of the cervix or non-melanoma skin cancer	☐ No	☐ Yes
Previous chemotherapy for cancer or other malignant disease	☐ No	☐ Yes
Charlton comorbidity index, excluding score for malignancy: (CCI) > 2, Comment: In patients 70-75 a CCI = 3 is allowed	☐ No	☐ Yes
Inadequate organ function, suggested by the following laboratory results: a. Absolute neutrophil count < 1,5 x 109/L b Platelet count < 100 x 109/L c Haemoglobin < 90 g/L d Total bilirubin greater than the upper limit of normal (ULN) unless the patient has documented Gilbert´s syndrome e ASAT (SGOT) and/or ALAT (SGPT) > 2,5 x ULN f ASAT (SGOT) and/or ALAT (SGPT) > 1,5 x ULN with concurrent serum alkaline phosphatase (ALP) > 2,5 x ULN g Serum creatinine clearance < 50 mL/min	☐ No	☐ Yes
Concurrent peripheral neuropathy of grade 3 or greater (NCI-CTCAE, Version 5.0)	☐ No	☐ Yes
Patient who is actively breast feeding	☐ No	☐ Yes
Assessed by the Investigator to be unable or unwilling to comply with the requirements of the protocol	☐ No	☐ Yes
Patients with known deficiency of the DPD-enzyme who completely lack DPD	☐ No	☐ Yes

Date Consent NordicTrip: Y M D

Consent Extra Biopy before Cycle 3: ☐ No ☐ Yes

Consent RNA-later Biopsies (BL and before C3): ☐ No ☐ Yes