

KURZPROTOKOLL
CA20977T

Öffentlicher Titel	Phase III Studie zu Nivolumab neoadjuvant und adjuvant bei nicht-kleinzelligem Lungenkrebs
Wissenschaftl. Titel	A Phase 3, Randomized, Double-blind Study of Neoadjuvant Chemotherapy plus Nivolumab versus Neoadjuvant Chemotherapy plus Placebo, followed by Surgical Resection and Adjuvant Treatment with Nivolumab or Placebo for Participants with Resectable Stage II-IIIB Non-small Cell Lung Cancer
Kurztitel	CA20977T
Studienart	multizentrisch, prospektiv, Therapiestudie, randomisiert, Pharma-Studie, doppelblind, zweiarmig
Studienphase	Phase III
Erkrankung	Lunge: Lungenkrebs: Nicht kleinzelliges Lungenkarzinom (NSCLC) - neoadjuvant
Einschlusskriterien	- Participants with suspected or histologically confirmed Stage IIA (> 4 cm) to IIIB (T3N2) non-small cell lung carcinoma (NSCLC) with disease that is considered resectable - No brain metastasis - Treatment-naïve for NSCLC (no prior systemic anti-cancer treatment) - Eastern Cooperative Oncology Group (ECOG) Performance Status of ≤ 1 - Ability to provide surgical or biopsy tumor tissue for biomarkers
Ausschlusskriterien	- Participants with an active, known or suspected autoimmune disease are excluded - Any positive test for hepatitis B virus or hepatitis C virus or human immunodeficiency virus (HIV) indicating acute or chronic infection - Any previous anti-cancer treatment including cytotoxic, IO treatment, targeted agents, or radiotherapy
Alter	18 - 99 Jahre
Prüfzentren	Krankenhaus Nordwest GmbH (Rekrutierung beendet) Klinik für Onkologie und Hämatologie Steinbacher Hohl 2-26 60488 Frankfurt am Main Dr. med. Akin Atmaca atmaca.akin@khnw.de
Sponsor	Bristol-Myers Squibb
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT04025879 EudraCT 2019-000262-38