KURZPROTOKOLL
Power AIO-STO-0309

Öffentlicher Titel	Cisplatin und 5-FU mit oder ohne Panitumumab bei nichtresekablem, fortgeschrittenem oder metastasiertem ESCC
Wissenschaftl. Titel	Eine offene, randomisierte Phase III-Studie zu Cisplatin und 5- Fluorouracil mit oder ohne Panitumumab bei Patienten mit nicht-resektablem, fortgeschrittenen oder metastasierten Plattenepitelkarzinom des Ösophagus
Kurztitel	Power AIO-STO-0309
Studienart	multizentrisch, prospektiv, randomisiert, offen/unverblindet, zweiarmig, Investigator Initiated Trial (IIT)
Studienphase	Phase III
Erkrankung	Verdauung: Magen-/Speiseröhrenkrebs (Magen-/Ösophaguskarzinom): Erstlinie
Ziele	- To demonstrate superiority of 5-fluorouracil, cisplatin and panitumumab over 5-fluorouracil and cisplatin alone in terms of overall survival in esophageal cancer - To compare treatment arms with respect to: - · Progression-free survival - · 1-year survival - · Response rate - · Safety and tolerability - · Quality of Life
Einschlusskriterien	- Signed written informed consent - Male or female - >18 years of age - Histologically proven squamous cell carcinoma of the esophagus, which is not curatively resectable - or locally recurrent disease and both not eligible - or definitive radiochemotherapy, or clearly metastatic disease (Tx, Nx, M1, locally unresectable T4, Nx, M0 or TX, N3, M0) - or macroscopically residual (post-resection) disease not eligible - for definitive radiochemotherapy - resectability has to be defined prior to chemotherapy according to local standards: The tumor is considered unresectable due to: T-stage, N-stage, performance status/nutritional status, comorbidity (pulmonary function, other), tumor location upper third of the esophagus, relation to other organs/structures), patient refusal, other reasons. - eligibility to definitive radiochemotherapy will be determined according to local standards based on the extent of disease, performance status/nutritional status, co-morbidity (pulmonary function, other), volume of neighboring organs within the radiation field, patient refusal, other reasons. - Measurable or non-measurable disease according to RECIST 1.1 5. ECOG 0-2 - Women of child-bearing potential must have a negative pregnancy test - Laboratory requirements - Hematology: - Absolute neutrophil count 71.5x109/L - Platelet count 7100x109/L - Leukocyte count > 3.0x109/L - Hemoglobin 7 9 g/dL or 5.59 mmol/l - Hepatic Function - Total bilirubin > 1.5 time the upper normal limit (UNL)

	- AST > 2.5xUNL in absence of liver metastases, or >5xUNL in presence of liver metastases - ALT > 2.5xUNL in absence of liver metastases, or >5xUNL in presence of liver metastases - Renal Function: - Creatinine clearance 750 mL/min according to Cockroft-Gault formula - Metabolic Function - Magnesium 7 lower limit of normal - Calcium 7 lower limit of normal.
Ausschlusskriterien	- Previous chemotherapy of esophageal cancer except for neoadjuvant treatment without recurrence within 6 months after the end of treatment - Concurrent radiotherapy involving target lesions used for this study. Concurrent palliative radiation for non-target lesions is allowed if other lesions are available outside the involved field. Previous pre-operative or post-operative radiotherapy is allowed. - Previous exposure to EGFR-targeted therapy - Other previous malignancy with exception of a history of a previous curatively treated basal cell carcinoma of the skin or pre-invasive carcinoma of the cervix or other curatively treated malignant disease without recurrence after at least 5 years of follow -up - Known brain metastases unless adequately treated (surgery or radiotherapy) with no evidence of progression and neurologically stable off anticonvulsants and steroids - Serious concomitant disease or medical condition that in the judgment of the investigator renders the subject at high risk of treatment complication or reduces the probability of assessing clinical effect. - Clinically significant cardiovascular disease (including myocardial infarction, unstable angina, symptomatic congestive heart failure, serious uncontrolled cardiac arrhythmia) £ 1 year before enrolment - Inadequate pulmonary function according to the Investigator’s judgment, history of interstitial lung disease e.g. pneumonitis or pulmonary fibrosis or evidence of interstitial lung disease on baseline chest CT scan. - Hearing loss > NCI-CTC V.3.0 Grade 3 - Subject pregnant or breast feeding, or planning to become pregnant within 6 months after the end of treatment. - Subject (male or female) is not willing to use highly effective methods of contraception (per institutional standard) during treatment and for 6 months (male or female) after the end of treatment. - Contraindications to receive any platin, 5-FU or panitumumab - Concurrent treatment with other experimental drugs or participation in another clinical trial with any investigational drug within 30 days prior to treatment start - Pregnancy or lactation - Known drug abuse/alcohol abuse - peripheral polyneuropathy > NCI-CTC V 3.0 Grade 2 - chronic inflammatory bowels diseases - Social situations limiting the compliance with the study requirements.
Alter	18 Jahre und älter
Fallzahl	300
Sponsor	AIO-Studien GmbH

Förderer	AIO-Studien GmbH
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT01627379 EudraCT 2010-020606-15
Links	Studien am Krankenhaus Nordwest