KURZPROTOKOLL
D2610C00004

Öffentlicher Titel	AZD4547 versus Paclitaxel bei fortgeschrittenem Magenkarzinom oder Karzinom des gastroösophagealen Übergangs
Wissenschaftl. Titel	A Randomised Open-Label Phase IIa Study to Assess the Efficacy and Safety of AZD4547 Monotherapy Versus Paclitaxel in Patients With Advanced Gastric or Gastro-oesophageal Junction Cancer With FGFR2 Polysomy or Gene Amplification (SHINE study)
Kurztitel	D2610C00004
Studienart	multizentrisch, prospektiv, randomisiert, offen/unverblindet, Pharma-Studie, zweiarmig
Studienphase	Phase II
Erkrankung	Verdauung: Magen-/Speiseröhrenkrebs (Magen-/Ösophaguskarzinom): Zweitlinie oder höher
Ziele	- Assessment of relative efficacy of AZD4547 compared with paclitaxel by comparison of the change in tumour size at 8 weeks (as measured by RECIST) in all patients and also in patients with FGFR2 amplified tumours (FISH 6) alone - Relative efficacy of AZD4547 compared with paclitaxel by assessment of progression free survival (measured by RECIST 1.1 or death), in all randomized patients and also in patients with FGFR2 amplified tumours (FISH 6) alone - Efficacy of AZD4547 vs paclitaxel by assessment of objective response rate (% of Patients with Complete or Partial Response prior to progression as measured by RECIST 1.1) in randomized patients and patients with FGFR2 amplified tumours (FISH 6) alone Assess the efficacy of AZD4547 and paclitaxel by assessment of the percentage of patients without progressive disease (as measured by RECIST 1.1) at 8 weeks - Investigate pharmacokinetics of AZD4547 in advanced gastric cancer patient population. - Investigate possible relationships between plasma AZD4547 and levels of phosphate - Investigate possible relationships between plasma AZD4547 and levels of bFGF - Investigate possible relationships between plasma AZD4547 and levels of FGF23 - Safety and tolerability of AZD4547 versus paclitaxel in terms of adverse events - Adverse events - Safety and tolerability of AZD4547 versus paclitaxel by assessing changes from baseline of Safety and tolerability of AZD4547 versus paclitaxel in terms of changes from baseline in vital signs
Einschlusskriterien	- Female or male aged 25 or over - Histological diagnosis of locally advanced or metastatic gastro adenocarcinoma (including adenocarcinoma of the lower third of the oesophagus or the gastro oesophageal junction) - Radiographically confirmed progression after 1 prior chemotherapy or chemoradiotherapy for gastric cancer. - Suitable for and expected to benefit from paclitaxel monotherapy. - At least one lesion, not previously irradiated, that at baseline is equal to or larger than 10mm in the longest diameter for non nodal lesions with ComputerisedTomography(CT) or Magnetic Resonance Imaging (MRI) - Provision of either an archival tumour sample or a fresh tumour sample for confirmation of FGFR2 polysomy/gene amplification by the sponsor approved laboratory. - Patients with FGFR2 polysomy or gene amplified tumours will be eligible for the main study
Ausschlusskriterien	- Prior exposure to AZD4547 or history of hypersensitivity other drugs similar in structure or class to AZD4547.

- Hypersensitivity to paclitaxel or formulated in cremaphor EL (polyoxyethylated castor oil)
- Major surgery, radiotherapy with wide field of radiation or any cancer treatment within 4 weeks before the first dose of the study treatment.
- With the exception of alopecia, any unresolved toxicities from prior therapy with a Common Terminology Criteria for AE (CTCAE) grade >1 at the time of starting study treatment.
- Blood and Echocardiogram (ECG) readings that are deemed to be abnormal by falling outside of the reference ranges in the protocol inclusion/exclusion section.
- Taking other regular medication that are predicted to interact with AZD4547 due to their route of metabolism

Alter	25 Jahre und älter
Molekularer Marker	FGFR
Status	Geschlossen
Sponsor	Astra Zeneca (Hauptsponsor)
Förderer	Astra Zeneca
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT01457846 (primäres Register) EudraCT 2010-023377-19
Therapie	AZD4547 paclitaxel
Links	Studien im Krankenhaus Nordwest