

KURZPROTOKOLL
D2610C00001

Öffentlicher Titel	Sicherheit und Verträglichkeit von AZD4547 bei Patienten mit fortgeschrittenen Tumoren
Wissenschaftl. Titel	A Phase I, Open-Label, Multicentre Study to Assess the Safety, Tolerability, Pharmacokinetics and Preliminary Anti-tumour Activity of Ascending Doses of AZD4547 in Patients With Advanced Solid Malignancies
Kurztitel	D2610C00001
Studienart	multizentrisch, prospektiv, offen/unverblindet, einarmig, Pharma-Studie
Studienphase	Phase I
Ziele	<ul style="list-style-type: none">- safety and tolerability of AZD4547- To characterise the pharmacokinetics (PK) of AZD4547 following a single administration and at steady state after dosing when given orally. To obtain a preliminary assessment of the anti tumour activity of AZD4547 by evaluation of tumour response using Response Evaluation Criteria in Solid Tumours (RECIST) criteria version 1.1
Einschlusskriterien	<ul style="list-style-type: none">- Estimated life expectancy of more than 12 weeks- The presence of a solid, malignant tumour that is resistance to standard therapies or for which no standard therapies exist- The tumour must have high levels of FGFR1 and/or FGFR2 receptors in a sample provided to the sponsor company for testing. Presence of a tumour of at least 1 cm in size that can be measured using at CT or MRI scan.- The tumour must have high levels of FGFR1 and/or FGFR2 receptor gene copy number in a sample provided to the sponsor company for testing- Presence of a tumour of at least 1 cm in size that can be measured using a CT or MRI scan
Ausschlusskriterien	<ul style="list-style-type: none">- Treatment with any other chemotherapy, immunotherapy or anticancer agents within 3 weeks before the first dose of study- An inability to be able to take the study medication- A bad reaction to AZD4547 or any drugs similar to it in structure or class
Alter	25 Jahre und älter
Molekularer Marker	FGFR
Status	Geschlossen
Sponsor	Astra Zeneca (Hauptsponsor)
Förderer	Astra Zeneca
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT00979134 (primäres Register) EudraCT 2009-012922-35
Therapie	AZD4547
Links	Studien im Krankenhaus Nordwest