KURZPROTOKOLL
1309dox15ct

Öffentlicher Titel	Phase I Studie Bioverfügbarkeit und -äauivalenz von pegyliertem, liposomalem Doxorubicin bei Brust- und Eierstockkrebs
Wissenschaftl. Titel	Characterisation of relative bioavailability and assessment of bioequivalence of a newly developed concentrate for solution for infusion containing pegylated liposomal doxorubicin hydrochloride (PLD) in comparison with a marketed reference in an open-label, randomised, balanced, single dose, two-way, cross-over trial in female patients including a two-stage approach
Kurztitel	1309dox15ct
Studienart	multizentrisch, prospektiv, Therapiestudie, randomisiert, offen/unverblindet, zweiarmig
Studienphase	Phase I
Erkrankung	Geschlechtsorgane: Krebserkrankungen der weiblichen Geschlechtsorgane: Eierstockkrebs (Ovarialkarzinom) - adjuvant Geschlechtsorgane: Brustkrebs: adjuvant
Einschlusskriterien	- sex: female - age: 18 and older - weight: at least 40 kg - advanced ovarian cancer or metastatic breast cancer requiring monotherapy with pegylated liposomal doxorubicin - an overall physical status of the subject allowing a minimum dose of 37.5 mg/m2 in accordance with the SmPC of Caelyx - having a haemogram which allows administration of doxorubicin, i.e. platelets > 75 000/l and neutrophile leucocytes > 1500/l - Karnofsky performance status at least 70 or higher - written informed consent, after having been informed about benefits and potential risks of the study, as well as details of the insurance taken out to cover the patient's participating in the study
Ausschlusskriterien	- Any other disease, which makes the patient unable to participate in the study - known allergic reactions to the active ingredient used or to constituents of the pharmaceutical preparations - patients with severe allergies or multiple drug allergies unless it is judged as not relevant for the clinical trial by the investigator - creatinine-clearance < 30 ml/min (MDRD formula) - bilirubin values > 3 mg/dl unless earlier administrations have shown that a minimum dose of 37.5 mg/m2 is tolerated by the subject (for details see SmPC of Caelyx; in case of liver metastases patients with concurrent elevation of bilirubin and liver enzymes up to 4 x the upper limit of the normal range may be enrolled - findings from ECG and/or assessment of LVEF which indicate an anthracycline-related cardiotoxic process which contradicts administration of liposomal doxorubicin in accordance with the requirements of the SmPC of Caelyx - positive anti-HIV-test (if positive to be verified by western blot), HBs-AG-test (if positive to be verified by test for HBc-IgM) or anti-HCV-test - any major surgery, radiotherapy, or chemotherapy other than doxorubicin within the last 21 days (limited palliative radiation allowed 2 weeks prior to the first dose; 4 weeks for whole brain radiotherapy) - chemotherapy regimens with delayed toxicity within the last 4 weeks (or within the last 6 weeks for prior nitrosourea or mitomycin C) - chemotherapy regimens given continuously or on a weekly basis with limited potential for delayed toxicity within the last 2 weeks

- concomitant use of any medication which may have an effect on the pharmacokinetics of doxorubicin (e.g. CYP450 inhibitors and/or inducers as rifampicin, barbiturates, ciclosporin, cimetidine or other e.g. paclitaxel, phenytoin, ritonavir) unless the investigator judges that the effect on the pharmacokinetics will be stable in both periods, e.g. due to sufficiently long and continued long-term use of the concomitant medication and/or a fixed administration scheme in relation to the administration of the IMP
- any medical condition or concomitant treatment/medication judged by the responsible oncologist as contraindicated Lack of suitability for the study
- participation in any clinical trial during the last 2 months prior to individual enrollment of the patient
- blood donation or other blood loss of more than 400 ml within the last 2 months prior to individual enrolment of the patient
- patients with anticipated problems of successfully drawing venous blood or with intravenous administration of IMP (e.g. due to poor vein conditions) For patients with childbearing potential only
- positive pregnancy test at screening examination
- pregnant or lactating women
- patients who do not agree to apply highly effective contraceptive methods (for details see chapter 13.2.1) Administrative reasons
- patients suspected or known not to follow instructions
- patients who are unable to understand the written and verbal instructions, in particular regarding the risks and inconveniences they will be exposed to during their participation in the clinical trial The exclusion criteria are chosen to assure that subjects with specific risks for administration of the IMPs and subjects with conditions, which may have an impact on pharmacokinetic parameters, cannot be included.

Alter	18 Jahre und älter
Status	Geschlossen
Prüfzentren	**Krankenhaus Nordwest GmbH** Institut für klinisch-onkologische Forschung Steinbacher Hohl 2-26 60488 Frankfurt am Main Prof. Dr. med. Salah-Eddin Al-Batran Tel: 069 7601 4420 albatran@khnw.de Camilla Scherer Tel: 069 7601 4280 Fax: 069 7601 36 55 scherer.camilla@khnw.de
Registrierung in anderen Studienregistern	EudraCT 2015-003975-30