KURZPROTOKOLL
E-Vita

Öffentlicher Titel	Wirksamkeit und Sicherheit von prophylaktischer Verabreichung von Doxycyclin +/- Vitamin K -Creme
Wissenschaftl. Titel	A Double Blind Placebo Controlled Randomized Phase II Study Evaluating the Efficacy and Safety of the Prophylactic Use of Doxycycline +/- Vitamin K Cream in First Line mCRC Patients Treated With Erbitux and FOLFIRI
Kurztitel	E-Vita
Studienart	multizentrisch, prospektiv, randomisiert, doppelblind, zweiarmig
Studienphase	Phase II
Erkrankung	Verdauung: Darmkrebs (Kolorektales Karzinom): sonstige Studien für Darmkrebs

Einschlusskriterien

- Written informed consent must be given
- Patient >= 18 years
- Histologically proven and measurable metastatic adenocarcinoma of the colon or rectum (according to modified RECIST criteria v.1.1)
- Patients eligible for Erbitux and FOLFIRI treatment K-Ras wild type tumour
- Metastatic disease
- Life expectancy of at least 12 weeks
- WHO performance status of 0 or 1
- Effective contraception for both male and female patients if the risk of conception exists
- Adequate organ function
- Adequate bone marrow, hepatic and renal function (Hemoglobin > 10.0 g/dL, platelet count > 100 x 109/L, absolute neutrophil count > 1.5 x 109/L; ALAT, ASAT < 2.5 x ULN (upper limit of normal range) or < 5x ULN in case of liver metastasis; Alkaline phosphatase < 2.5 x ULN; Total bilirubin < 1.5 x ULN; Creatinine clearance > 50 mL/min (calculated according to Cockcroft and Gault formula)).

Ausschlusskriterien

- Prior treatment for metastatic disease (adjuvant therapy with 5-FU/oxaliplatin based regimens) allowed if stopped 6 months prior to registration on study
- Prior treatment with EGFR inhibitor
- Surgery (excluding diagnostic biopsy) or irradiation within 4 weeks prior to study entry
- Administration of any investigational drug or agent/procedure, i.e. participation in another trial within 4 weeks before beginning treatment with study drugs
- Concurrent chronic systemic immune therapy, chemotherapy, radiation therapy or hormone therapy not indicated in the study protocol
- Any active dermatological condition > grade 1 at baseline possibly interfering with or influencing the results or conduct of the present study
- Brain metastasis (known or suspected)
- Significant impairment of intestinal resorption (e.g. chronic diarrhea, inflammatory bowel disease)
- Any other uncontrolled concomitant illness, including serious uncontrolled intercurrent infection
- Severe or uncontrolled cardiovascular disease (congestive heart failure NYHA III or IV, unstable angina pectoris, history of myocardial infarction within the last twelve months, significant arrhythmias)
- Known allergy or any other adverse reaction to any of the study drugs or to any related compound.
- Any organ allograft requiring immunosuppressive therapy.
- Pregnancy (absence to be confirmed by serum/urine beta human chorion gonadotrophin (HCG)) or breast-feeding.

	- Other previous malignancy within 5 years, with exception of a history of a previous basal cell carcinoma of the skin or pre-invasive carcinoma of the cervix surgically cured or adequately treated. - Known drug abuse / alcohol abuse - Legal incapacity or limited legal capacity - Any psychological, familial, sociological or geographical condition potentially hampering compliance with the study protocol and followup schedule; those conditions should be discussed with the patient before registration in the trial. - Medical or psychological condition which, in the opinion of the investigator, would not permit the patient to complete the study or meaningfully sign informed consent. - Known M. Meulengracht (Gilbert´s disease) or DPD-insufficiency - Known coagulation disorders - Ongoing or planned treatment with coumarin derivates
Alter	18 Jahre und älter
Molekularer Marker	KRAS wt
Prüfzentren	**Krankenhaus Nordwest GmbH** (Rekrutierung beendet) 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.salah@khnw.de
Sponsor	Universitätsklinikum Mannheim (Hauptsponsor)
Förderer	Universitätsklinikum Mannheim
Registrierung in anderen Studienregistern	EudraCT 2010-021940-16 ClinicalTrials.gov NCT01345526 (primäres Register)