

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 $> 100 \times 10^9/L$, absolute neutrophil count $> 1.5 \times 10^9/L$; ALAT, ASAT $< 2.5 \times$ ULN (upper limit of normal range) or $< 5 \times$ ULN in case of liver metastasis; Alkaline phosphatase $< 2.5 \times$ ULN; Total bilirubin $< 1.5 \times$ 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 $> \text{grade } 1$ 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.

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- 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 derivatives

Alter	18 Jahre und älter
Molekularer Marker	KRAS wt
Sponsor	Universitätsklinikum Mannheim (Hauptsponsor)
Förderer	Universitätsklinikum Mannheim
Registrierung in anderen Studienregistern	EudraCT 2010-021940-16 ClinicalTrials.gov NCT01345526 (primäres Register)