

## **KURZPROTOKOLL** **E-Vita**

<b>Öffentlicher Titel</b>	Wirksamkeit und Sicherheit von prophylaktischer Verabreichung von Doxycyclin +/- Vitamin K -Creme
<b>Wissenschaftl. Titel</b>	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
<b>Kurztitel</b>	E-Vita
<b>Studienart</b>	multizentrisch, prospektiv, randomisiert, doppelblind, zweiarmig
<b>Studienphase</b>	Phase II
<b>Erkrankung</b>	Verdauung: Darmkrebs (Kolorektales Karzinom): sonstige Studien für Darmkrebs
<b>Einschlusskriterien</b>	<ul style="list-style-type: none"><li>- Written informed consent must be given</li><li>- Patient <math>\geq</math> 18 years</li><li>- Histologically proven and measurable metastatic adenocarcinoma of the colon or rectum (according to modified RECIST criteria v.1.1)</li><li>- Patients eligible for Erbitux and FOLFIRI treatment K-Ras wild type tumour</li><li>- Metastatic disease</li><li>- Life expectancy of at least 12 weeks</li><li>- WHO performance status of 0 or 1</li><li>- Effective contraception for both male and female patients if the risk of conception exists</li><li>- Adequate organ function</li><li>- Adequate bone marrow, hepatic and renal function (Hemoglobin <math>&gt;</math> 10.0 g/dL, platelet count <math>&gt;</math> <math>100 \times 10^9/L</math>, absolute neutrophil count <math>&gt;</math> <math>1.5 \times 10^9/L</math>; ALAT, ASAT <math>&lt;</math> <math>2.5 \times</math> ULN (upper limit of normal range) or <math>&lt;</math> <math>5 \times</math> ULN in case of liver metastasis; Alkaline phosphatase <math>&lt;</math> <math>2.5 \times</math> ULN; Total bilirubin <math>&lt;</math> <math>1.5 \times</math> ULN; Creatinine clearance <math>&gt;</math> 50 mL/min (calculated according to Cockcroft and Gault formula)).</li></ul>
<b>Ausschlusskriterien</b>	<ul style="list-style-type: none"><li>- Prior treatment for metastatic disease (adjuvant therapy with 5-FU/oxaliplatin based regimens) allowed if stopped 6 months prior to registration on study</li><li>- Prior treatment with EGFR inhibitor</li><li>- Surgery (excluding diagnostic biopsy) or irradiation within 4 weeks prior to study entry</li><li>- Administration of any investigational drug or agent/procedure, i.e. participation in another trial within 4 weeks before beginning treatment with study drugs</li><li>- Concurrent chronic systemic immune therapy, chemotherapy, radiation therapy or hormone therapy not indicated in the study protocol</li><li>- Any active dermatological condition <math>&gt;</math> grade 1 at baseline possibly interfering with or influencing the results or conduct of the present study</li><li>- Brain metastasis (known or suspected)</li><li>- Significant impairment of intestinal resorption (e.g. chronic diarrhea, inflammatory bowel disease)</li><li>- Any other uncontrolled concomitant illness, including serious uncontrolled intercurrent infection</li><li>- 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)</li><li>- Known allergy or any other adverse reaction to any of the study drugs or to any related compound.</li><li>- Any organ allograft requiring immunosuppressive therapy.</li><li>- Pregnancy (absence to be confirmed by serum/urine beta human chorion gonadotrophin (HCG)) or breast-feeding.</li></ul>

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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 derivates

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