

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	<ul style="list-style-type: none">- Written informed consent must be given- Patient \geq 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	<ul style="list-style-type: none">- 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.

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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

Alter

18 Jahre und älter

Molekularer Marker

KRAS wt

Prüfzentren

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Sponsor

Universitätsklinikum Mannheim (Hauptsponsor)

Förderer

Universitätsklinikum Mannheim

Registrierung in anderen Studienregistern

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ClinicalTrials.gov NCT01345526 (primäres Register)