

## **KURZPROTOKOLL PROCAPP**

<b>Öffentlicher Titel</b>	Phase III Studie zu Mapsial® vs Urea Handcreme als Prophylaxe gegen "hand-foot" Syndrom (HFS) bei gastrointestinalen Tumoren oder Brustkrebs
<b>Wissenschaftl. Titel</b>	A Randomized, Open-label Phase III Trial of Mapsial® Versus an Urea Hand-foot Cream as Prophylaxis for Capecitabine-induced Hand-foot Syndrome in Patients With Gastrointestinal Tumors or Breast Cancer
<b>Kurztitel</b>	PROCAPP
<b>Studienart</b>	multizentrisch, prospektiv, randomisiert, offen/unverblindet, zweiarmig, Investigator Initiated Trial (IIT)
<b>Studienphase</b>	Phase III
<b>Erkrankung</b>	Verdauung: Bauchspeicheldrüsenkrebs (Pankreaskarzinom): weitere Verdauung: Magen-/Speiseröhrenkrebs (Magen-/Ösophaguskarzinom): weitere Verdauung: Gastrointestinale Stromatumoren (GIST): weitere Geschlechtsorgane: Brustkrebs: sonstige Studien für Brustkrebs Verdauung: Darmkrebs (Kolonreales Karzinom): weitere Verdauung: Leberkrebs (Hepatozelluläres Karzinom): weitere
<b>Ziele</b>	<ul style="list-style-type: none"><li>- To assess the efficacy of Mapsial to prevent hand-foot syndrome (HFS) of any grade in patients treated with capecitabine based on a standardised patient diary</li><li>- To compare efficacy and safety with respect to: 1. HFS by grade over time 2. Time to development of HFS &gt; grade 1 3. Time to change of HFS treatment strategy 4. Time to capecitabine dose reduction or dose interruption 5. Evaluation of capecitabine dose intensity 6. QoL analyses (EORTC QLQ C30 and DLQI)</li></ul>
<b>Einschlusskriterien</b>	<ul style="list-style-type: none"><li>- Signed written informed consent</li><li>- Male or female <math>\geq 18</math> years of age</li><li>- Patients with gastrointestinal tumors or breast cancer who will be treated with capecitabine according to label</li><li>- Palliative or adjuvant chemotherapy with capecitabine</li><li>- Life expectancy of least 12 weeks</li><li>- WHO performance status 0-2</li><li>- Adequate contraception</li><li>- Willingness to fill in QoL forms</li><li>- Laboratory requirements: 1. Platelet count <math>\geq 100 \times 10^9/L</math> 2. Leukocyte count <math>&gt; 3.0 \times 10^9/L</math> 3. Hemoglobin <math>\geq 10.0</math> g/dL</li></ul>
<b>Ausschlusskriterien</b>	<ul style="list-style-type: none"><li>- Previous chemotherapy with capecitabine or liposomal doxorubicine, or any other substance, i.e. tyrosine kinase inhibitors (such as sorafenib and sunitinib) that may induce HFS</li><li>- Radiotherapy or surgery within 4 weeks before start of treatment</li><li>- Resolution of all chemotherapy- or radiotherapy-related toxicities to grade 1 or lower except for stable sensory neuropathy &lt; grade 2 and alopecia, excluding dermatological toxicities</li><li>- Dermatologic diseases that could interfere with the result of the clinical trial</li><li>- Known drug/ alcohol abuse</li><li>- Pregnant or breast feeding patients</li><li>- Participation in another clinical trial and patient received investigational drug within the last 30 days prior to treatment start (i.e. follow-up within a preceding trial is not exclusionary)</li><li>- Known allergic reactions to any of the ingredients of the ointments or capecitabine</li></ul>
<b>Alter</b>	18 Jahre und älter
<b>Status</b>	Rekrutierung beendet

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<b>Fallzahl</b>	10
<b>Sponsor</b>	AIO-Studien GmbH
<b>Förderer</b>	AIO-Studien GmbH
<b>Registrierung in anderen Studienregistern</b>	ClinicalTrials.gov NCT01626781