

<b>Studienname</b>	<b>TRIO 048</b> <b>An Open-Label, Randomized, Non-Comparative Phase 2 Study of ARV-471 or Anastrozole in Post-Menopausal Women With ER+/HER2- Breast Cancer in the Neoadjuvant Setting</b>
<b>Sponsor/ Studiencode</b>	ARVINAS, Pfizer ARV-471 (PF-07850327)
<b>Setting</b>	HER2 neg. eBC, neoadjuvante Therapie
<b>Primäres Studienziel</b>	Effekt auf Ki-67 Expression
<b>Studiendesign</b>	<b>Experimental: ARV-471 monotherapy</b> ARV-471 taken once daily until surgical resection Procedure: Surgical resection of breast tumor Participants will have surgical resection approximately 5.5 months after starting treatment (C6D18 ± 14 days)  <b>Active Comparator: Anastrozole monotherapy</b> Anastrozole 1mg taken once daily until surgical resection Procedure: Surgical resection of breast tumor Participants will have surgical resection approximately 5.5 months after starting treatment (C6D18 ± 14 days)
<b>Einschluss- kriterien (Auswahl)</b>	<ul style="list-style-type: none"> <li>• Post-menopausale Patientin</li> <li>• T1c-4c, NO-2 <b>und</b> Tumor mindestens 15 mm in der Bildgebung</li> <li>• HR pos. HER2 neg. nicht metastasiertes/ frühes Mammakarzinom</li> <li>• Ki-67 ≥ 5%</li> <li>• Erneute Biopsie unter Therapie</li> </ul>
<b>Ausschluss- kriterien (Auswahl)</b>	<ul style="list-style-type: none"> <li>• Maligne Vorgeschichte &lt;3 Jahre</li> <li>• Kardiale Vorgeschichte &lt;6 Monate</li> <li>• QTcF &gt; 470 msec</li> </ul>
<b>Teilnehmende Zentren</b>	➤ KEM Essen