AOU Città della Salute e della Scienza di Torino – PO Molinette

Titolo:	Studio randomizzato, in doppio cieco, controllato con placebo, di fase III su saruparib adiuvante (AZD5305) in pazienti con carcinoma prostatico localizzato ad alto rischio con mutazione BRCA che ricevono radioterapia con terapia di deprivazione androgenica (EvoPAR-Prostate02)
Patologia:	Carcinoma prostatico ad alto o altissimo rischio BRCA mutato
Tipo di Studio:	Interventistico, multicentrico, randomizzato, doppio cieco
Fase:	Fase III
Principali criteri di inclusione:	Participant must have a histologically documented diagnosis of prostate adenocarcinoma Participants with newly diagnosed high-risk and very high-risk (localised/locally advanced) prostate cancer or participants with a high-risk BCR following radical prostatectomy Provision of a FFPE tumour tissue sample Provision of a FFPE tumour tissue sample All participants will be required to have a CT or MRI and a bone scan following the completion of their planned RT. This screening scan must confirm no evidence of disease or evidence of disease confined to the pelvis (M0), as assessed by a central reader All participants will be required to have a PSMA-PET following the completion of their planned RT. ECOG performance status of 0 or 1 with no deterioration over the 2 weeks prior to randomisation Adequate organ and bone marrow function
Principali criteri di esclusione:	Participants with a history of MDS/AML or with features suggestive of MDS/AML Participants with any known predisposition to bleeding Any history of persisting (> 2 weeks) severe cytopenia due to any cause (eg, absolute neutrophil count < 0.5 × 109 /L or platelets < 50 × 109 /L). Refractory nausea and vomiting, chronic gastrointestinal diseases, inability to swallow the formulated product or previous significant bowel resection that would preclude adequate absorption of saruparib and/or abiraterone. History of another primary malignancy
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