ICON9: Randomised Trial of Cediranib and Olaparib Maintenance in Patients with Relapsed Platinum Sensitive Ovarian Cancer

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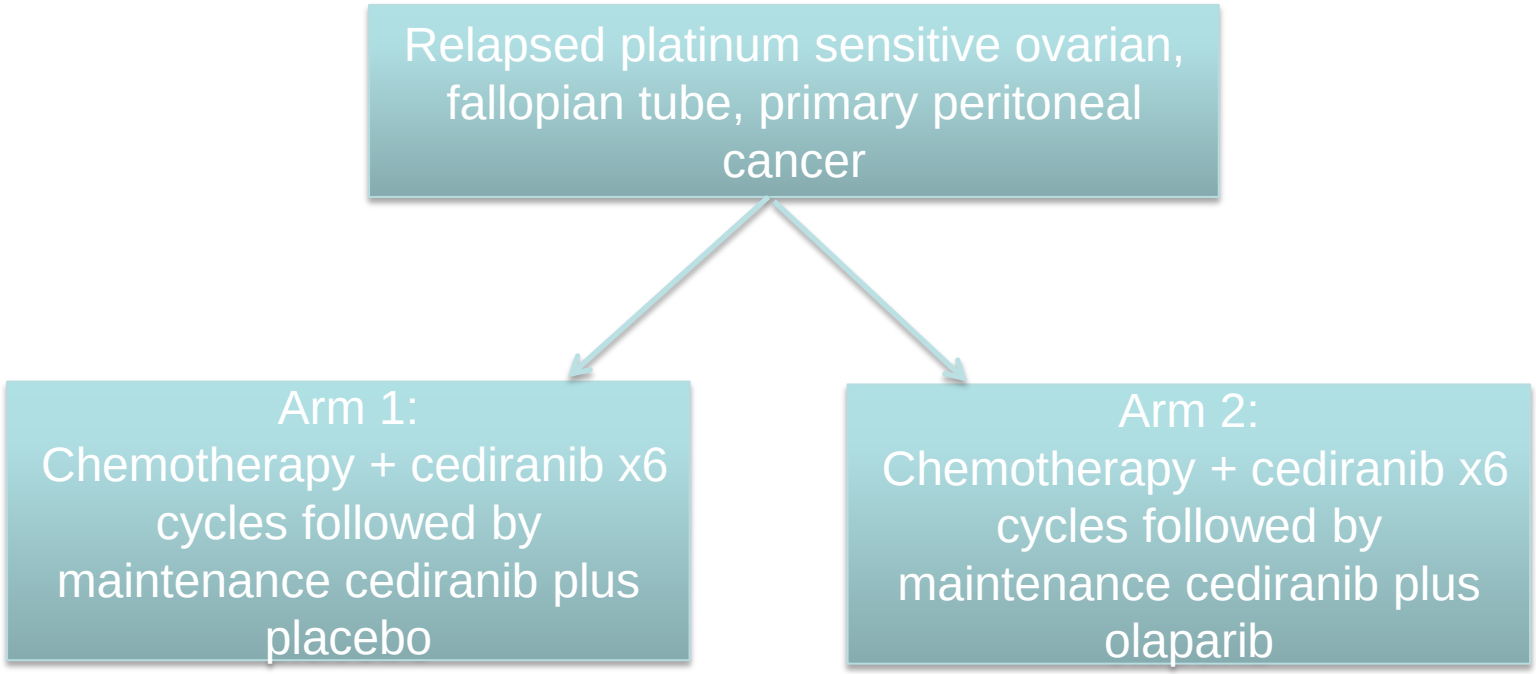
An Organization of International Cooperative Groups for Clinical Trials in Gynecologic Cancers

Trial Schema



Stratified by 6-12 vs >12 month progression free interval; HRD or no HRD; surgery vs no surgery at relapse prior to chemotherapy; whether patients had prior bevacizumab or not

Cediranib: 20 mg OD
Olaparib: 300 mg BD

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Study Objectives/Endpoints

To assess the efficacy of **maintenance cediranib in combination with olaparib**

	End points
Primary Objective	PFS (RECIST v1.1) OS
Secondary objectives	Progression free survival by CA125 - GCIG criteria
To assess the safety and tolerability of cediranib in combination with olaparib	Adverse events using CTCAE v4.0 Quality of Life (EORTC QLQ-C30, OV-28 and MOST questionnaire) Health Economics (EQ5D)
Activity of subsequent platinum based chemotherapy	PFS2

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Time lines

- Feb 2014: UK NCRI CSG approval
- Nov 2014: Outline CTAAC submission successful
- AZ supportive of study-exact contribution TBC
- 30-40 sites UK
- 20 international sites from 2-4 countries
- May 2015: Full CTAAC application submitted