

Trial setting: Recurrent Ovarian Cancer

Trial Model: Academic (A)

Trial status – Developmental stage

Study Design: Phase II Open Label Randomised Controlled Trial

Peer Review: In process, ongoing

Groups: KolGo Trg (Kolkata Gynecology Oncology Trials and Translational research group, India)

Protocol number: (KolGo-PROVAR-003)

Sponsor(s): KolGo Trg

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Background-

Ovarian cancer accounts for about 4% of worldwide cancer incidence and mortality among women. Current therapy for patients with advanced ovarian cancer includes initial cytoreductive surgery followed by a platinum- and taxane-based chemotherapy regimen or neo-adjuvant chemotherapy followed by Interval cytoreduction and adjuvant chemotherapy. Most patients have disease recurrence at variable periods of time and some of the recurrences are detected only with rising ca125 levels even when they are asymptomatic. It is debatable whether further treatment including chemotherapy is needed at this stage as previous trials have not shown any survival benefit. On the other hand, leaving the recurrent disease too long for symptoms to appear might lead to a point where opportunity for adequate treatment maybe lost. Hormonal treatment which is often given by oral drugs has shown to be beneficial in some patients with ovarian cancer which have hormone receptors. Therefore we are proposing a study to see whether hormonal therapy if started in patients with asymptomatic recurrence could be beneficial to improve Quality of Life and Time to Progress to subsequent symptoms or treatment. We propose to conduct Randomised Phase II Study where the control arm would be the standard of care treatment which is currently only Physician counselling and observation. We will also assess the effect of this intervention in reducing anxiety, stroke distress for both the patient and

Objective-

Evaluating the efficacy [time to progression of disease (clinical, biochemical and radiological)] and safety of using hormone therapy (intervention) in asymptomatic women with a rise in CA 125 but no measurable disease versus physician's counselling for observation (control)in ovarian cancer.

Proposed study plan summary

Patients who have recurred after standard therapy in with High grade/ low grade serous/ serous ovarian & high grade endometrioid ovarian cancer with rising trend of Ca 125 be screened as per I/E criteria

