Pet Therapy

by | WENDY BORST

They always say that life changes when the kids leave and the dog dies, which proved true in my case, even if there were still six more dogs! I remember sitting at my computer wondering what I was going to do with the rest of my life and thinking that I had a rescue standard poodle named Roo who was born doing "people therapy". Pet Therapy was something that had always been of interest to me and maybe now was the time. I started researching and training, and before long had my "Angel in a poodle suit" certified and ready to go.

Pet Therapy comes in many shapes and sizes, as do the dogs who do it. I now work with three certified therapy dogs and have one who is ready to go once testing starts again. Teams can work in a multitude of sites including hospitals, skilled nursing facilities, memory care, libraries, schools, universities, corporate settings, shelters- the list goes on and on. As someone who was a practice manger for an oncology office, I wondered whether it might be useful in a chemotherapy/infusion setting as well. We started in a small office, in very close quarters and despite that, I was overwhelmed with the enthusiasm and pleasure that greeted our visits. I also noted that patients that were sitting alone and not interacting with others, found that they had common ground and something to chat about with their fellow patients. Suddenly, the whole atmosphere in the room changed and we saw that this interaction transformed into support for each other.

Arizona Oncology now has teams at almost all of their offices in the Valley and in Northern Arizona. We also try to expand our continuity by visiting patients in both the hospital and office settings. Often patients do not remember our names, but they always remember the dogs! We look forward to continuing to grow our program and are always looking for new volunteer teams who would like to join us - those who already have certified dogs and those who would like to get started in the process. If interested please contact Wendy Borst at 602-770-3486 for information.

Genetic Counseling Referral Criteria

Refer patients that meet any of the following criteria:

LYNCH SYNDROME

- ☐ Abnormal Lynch tumor screen
- ☐ Two or more colon, uterine or other Lynch related tumors* in same person
- ☐ Colon or uterine cancer at or before age 50
- ☐ 3 or more family members on same side of the family with colon, uterine or other Lynch-related tumors*

Note: Universal Lynch screening is recommended for all uterine and colon tumors

**Colon, uterine, ovarian, gastric, pancreatic, urinary tract, sebaceous tumor and brain tumors*

HEREDITARY BREAST AND OVARIAN CANCER

- ☐ Breast cancer at or before age 50
- ☐ Triple negative breast cancer at or before age 60
- ☐ Two primary breast cancers in the same person
- ☐ Ovarian (including fallopian tube or primary peritoneal cancer) at any age
- ☐ Prior negative BRCA1/2 testing
- ☐ Any pancreatic cancer patient
- ☐ Any metastatic prostate cancer patient
- ☐ 3 or more relatives with breast, ovarian, pancreatic &/or aggressive prostate cancer on the same side of the family
- ☐ Ashkenazi Jewish ancestry with personal or family history of breast, ovarian or pancreatic cancer

Breast Cancer includes DCIS and Invasive Cancers.

Other Criteria

- ☐ 10-20 total colon polyps
- ☐ Multiple hamartomatous or Juvenile GI polyps
- ☐ Rare tumors such as medullary thyroid carcinoma, paragangliomas or pheochromocytomas
- ☐ Known gene mutation in family

Access the online pedigree tool:
FHQ.ROOTOUTCANCER.COM

To refer a patient:
Phoenix: 480-223-9828 Tucson: 520-531-8967

Gyn Oncology Offices

BILTMORE CANCER CENTER
2222 E. Highland Ave., Suite 400, Phoenix, AZ 85016
Matthew Borst, MD, Heather Dalton, MD
Brad Monk, MD, Lyndsay Willmott, MD

DEER VALLEY
19646 N. 27th Ave., Suite 403, Phoenix, AZ 85027
Shana Wingo, MD, Dennis Scribner, MD

EAST MESA
6424 East Broadway, Mesa, AZ 85206
Snehal Bhoola, MD, Dana Chase, MD

EAST VALLEY CANCER CENTER
Medical, Gynecologic & Radiation Oncology, and Hematology
7695 South Research Dr., Tempe, AZ 85284
Snehal Bhoola, MD, Dana Chase, MD

GOODYEAR
Medical Oncology & Hematology, Gynecologic Oncology
13555 W. McDowell Rd., Suite 206, Goodyear, AZ 85395
Heather Dalton, MD

SCOTTSDALE
Gynecologic Oncology
10197 N. 92nd Street, Suite 101, Scottsdale, AZ 85258
Mike Janicek, MD

SCOTTSDALE
Medical & Gynecologic Oncology, and Hematology
10460 N. 92nd Street, Suite 402, Scottsdale, AZ 85258
Dennis Scribner, MD

TUCSON - WILMOT
603 N. Wilmot Road, Suite 151, Tucson, AZ 85711
Joseph Buscema, MD
Casandra Liggins, MD (Advanced Gyn Practitioner)

TUCSON - ORANGE GROVE
1845 W. Orange Grove, Bldg. 2, Tucson, AZ 85704
Alton Hallum, III, MD, Candice Lewis, MD

PHOENIX & NORTHERN ARIZONA

TO REFER A PATIENT:
For Drs. Bhoola, Borst, Chase, Dalton, Monk and Willmott
Phone: 888-972-CURE (2873) Fax: 602-283-3059

TO REFER A PATIENT:
For Drs. Wingo and Scribner
Phone: 623-879-4477 Fax: 623-879-4455

TO REFER A PATIENT:
For Dr. Janicek
Phone: 480-993-2950 Fax: 480-993-2957

TUCSON & SOUTHERN ARIZONA

TO REFER A PATIENT:
For Drs. Buscema and Liggins
Phone: 520-886-0206 Fax: 520-886-0829

TO REFER A PATIENT:
For Drs. Hallum and Lewis
Phone: 520-531-8967 Fax: 623-582-5300

Snehal Bhoola, MD

Matthew Borst, MD

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Dana Chase, MD

Heather Dalton, MD

Alton Hallum, MD

Mike Janicek, MD

Candice Lewis, MD

Bradley Monk, MD

Dennis R. Scribner, Jr., MD

Lyndsay Willmott, MD

Shana Wingo, MD

Arizona Oncology ■ 888.972.CURE ■ July 2020

GynOncology UPDATE

Risk Reduction Bilateral Salpingo-Oophorectomy: RRBSO

by | MATTHEW BORST, MD AND CASANDRA LIGGINS, MD

A convergence of insights from Genetics, Histopathology, Molecular Biology and Clinical Medicine have provided the opportunity to prevent up to 24% of cases of ovarian cancer.

Background

It is well known that hereditary breast and ovarian cancer is associated with BRCA1 and BRCA2 genetic alterations which predispose to familial clusters of malignancy. Multiple additional related genes are now also included in standard multigene panels that identify other, though less penetrant, ovarian cancer risk markers. Following identification of the BRCA1 gene (1994) and BRCA2 gene (1995) and with the knowledge that alterations of those genes lead to defective repair of double stranded DNA breaks, attempts have been made to further clarify the etiology of ovarian malignancy. It was noted that the incidence of ovarian malignancy diminished after benign pelvic surgeries (including hysterectomy and bilateral tubal ligation). It became clear that removal of the fallopian tubes and ovaries for patients with deleterious alterations of the BRCA genes would provide the opportunity for cancer prevention. The RRBSO procedure was initially referred to as "prophylactic surgery". Due to the underlying small residual risk for primary peritoneal cancer (despite BSO), ACOG has recommend the BSO procedure for cancer prevention to be characterized (and consented) as "risk reduction surgery". Remarkably, BSO also confers an additional significant 50-70% risk-reduction benefit for breast cancer in women with both inherited predisposition, and those without.

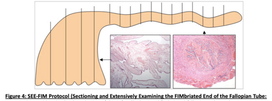

Figure 4: SEE-FIM Protocol (Sectioning and Extensively Examining the FIMbriated End of the Fallopian Tube: Amputation and longitudinal sectioning of the infundibulum and fimbriated fallopian tube and transverse sectioning of the isthmus and ampulla at 2-3 mm intervals allowing extensive examination.

Article reference #5

Continued on page 2

WELCOME

Welcome to Arizona Oncology's The Gyn Oncology Update newsletter. We are dedicated to educate and serve patients in our community. We hope you enjoy the educational content presented within. If you have any questions or feedback, please do not hesitate to contact us.

In This ISSUE

ARIZONA ONCOLOGY
The US Oncology Network

(cont'd) Risk Reduction Bilateral Salpingo-Oophorectomy

Importance

The risk for developing ovarian cancer in the general risk population is estimated at 1.3-1.6%. Lifetime risk of cancer of the ovary/fallopian tube/peritoneum for patients with proven genetic risk factors is markedly elevated. BRCA1 and BRCA2 deleterious alterations are present in between 1/300-1/500 women in the United States and account for 15-18% of ovarian cancer cases. In general, the risk estimate for women with BRCA1 mutations is 40%. The general risk estimated for women with BRCA2 alterations is 20%. For certain specific alterations the individual risk can even be higher.

The USPSTF has concluded that the net benefit of risk assessment, genetic testing and the implementation of risk reducing strategies outweighs the harms in women who have personal or familial history corresponding with an increased risk for harboring BRCA1 or BRCA2 pathogenic mutations.

Histologic and Molecular Evidence for Ovarian Carcinogenesis

The SEE-FIM protocol (Serial End Evaluation of the Fimbriae & ovaries) was developed to perform enhanced pathological evaluation of specimens from RRBSO for patients identified with increased genetic risk factors. Registries of results from the SEE-FIM protocol detected occult/micro carcinomas in approximately 4% of risk reduction surgical specimens. They also identified serous tubal intraepithelial carcinomas (STIC) lesions that were estimated to be a precursor to 30-40% of high grade serous ovarian cancers (HGSOC). These studies identified the fallopian tube as the likely precursor lesion for many HGSOC cases. Dr. Crum and colleagues provide histologic and molecular genetic evidence outlining 3 independent pathways for serous carcinogenesis of the ovaries/tubes/peritoneum. The first pathway (figure 1) identifies an early cancer originating within a surface ovarian cortical inclusion cyst. That lesion can proceed to invade the ovarian cortex and metastasize. The second pathway (figure 2) supports that HGSOC can form from early serous proliferation (ESP lesions) or from STIC lesions that undergo malignant transformation with metastatic potential. The third pathway (figure 3) proceeds when early serous proliferation (ESP) lesions in the fallopian tube spread to the peritoneum ("precursor escape") where the lesion can then evolve into invasive malignancy which can then metastasize back to the fallopian tubes or ovaries. In each case, the observations are supported by demonstrating p53 abnormalities in the ESP lesions and STIC lesions. P53 lesions are one of the molecular hallmarks of HGSOC.

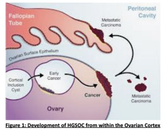

Figure 1: Development of HGSOC from within the Ovarian Cortex

Gyn Oncology / Feb 2019 /Vol 152, No 2 /pp: 426-433 / Crum et al

Article reference #4

Candidates for RRBSO

Registries of patients with BRCA1 and BRCA2 deleterious alterations who underwent RRBSO demonstrated an overall 80-90% cancer risk reduction. Careful identification of candidates for the procedure and the specific components of the procedure were evaluated and defined. Candidates were identified by taking careful personal and family medical histories. According to the USPSTF, those patients are then recommended to have counselling with a certified genetics counselor (CGC) and to have molecular testing for identifiable genetic risk factors.

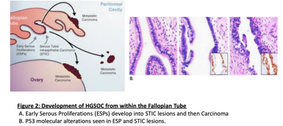

Figure 2: Development of HGSOC from within the Fallopian Tube
A. Early Serous Proliferations (ESPs) develop into STIC lesions and then Carcinoma
B. P53 molecular alterations seen in ESP and STIC lesions.

Article reference #4

Possible consultation with a gyn oncologist is also recommended. Candidates can then sign informed consent for RRBSO. The procedure can usually be accomplished with laparoscopic surgery.

Test of Principle: Results of RRBSO

In the general risk population, epidemiologic data from the Swedish Cancer Registry has demonstrated the clinical benefit for "opportunistic salpingectomy" as a cancer prevention method. 10 year follow up data for greater than 44,000 patients undergoing "opportunistic" bilateral salpingectomy show a 61% reduction in subsequent ovarian cancer risk when compared to a matched control population (RR=0.39). For the population with increased risk

(cont'd) Risk Reduction Bilateral Salpingo-Oophorectomy

due to identifiable genetic risk factors (principally BRCA1 and BRCA2), multiple studies have shown that RRBSO can reduce the lifetime risk of ovarian/tubal/peritoneal cancer by 80-90%. Occult micro carcinomas were also detected in

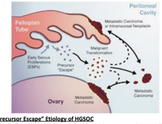

Figure 3: "Precursor Escape" Etiology of HGSOC
ESP lesions in the fallopian tube "escape" to the peritoneum, undergo malignant transformation and manifest as peritoneal cancer or metastasize to the fallopian tube or ovary.
Article reference #4

4% of the cases. Early identification and treatment of these lesions demonstrated reduced mortality. The persistent small residual risk for peritoneal cancer (approx. 10%) lends support for the "precursor escape" theory whereby occult molecular precursor lesions in the peritoneum may evolve into malignancy.

Components of the SEE-FIM protocol (figure 4)
The USPSTF and ACOG recommend a graded approach to identify candidates for RRBSO. Genetic risk assessment using a validated risk assessment tool allows identification of patients with elevated risk based on personal and family history. Genetic counseling is recommended to allow for appropriate pretest and post-test counseling as well as genetic mutation testing and establishing consultation with necessary specialists such as a gyn oncologist.
Adherence to the surgical protocol endorsed by the NCCN and ACOG allows for adequate identification of an occult neoplasm and enhances potential survival benefit. In most cases, performed laparoscopically, thorough evaluation of the upper abdomen and pelvic cavity should be performed and the bilateral adnexa fully described. Abdominal pelvic washings for cytology (using saline) is required as is the complete removal of the fallopian tubes and ovaries. Ligation of the ovarian vessels 2-3 cm proximal to the ovaries is recommended in order to remove any occult primordial oogonia that may be present adjacent and lateral to the ovary. Our personal recommendation (authors) is to initiate the RRBSO at the uterine cornu. Identification of the ureter and ovarian vessels is facilitated by gently moving the adnexa anteriorly, medially and superiorly during dissection of the mesosalpinx. This technique allows better separation of the ovarian/IP vessels and the ureter at the pelvic brim, which promotes protection of the ureters and allows full excision of the adnexa. Unambiguous communication between the surgeon and pathologist is necessary to confirm that the adnexal tissue is evaluated extensively using the SEE-FIM protocol. Written and verbal communication with the pathologist specifically requesting SEE-Fim protocol is recommended. The Sectioning and Extensively Examining the FIMbriae and ovaries protocol (SEE-FIM) is the standard of care and is necessary to rule out the presence of occult neoplasm.

Conclusion
Predisposing familial or genetic risk related to deleterious alterations of the BRCA1 or BRCA2 genetic loci are associated with 15-18% of cancers originating in the ovary/fallopian tube or peritoneum. An additional 2-6% of these cancers have alternative deleterious genetic risk factors which include: (BARD1/BRIP1/CHEK1/CHEK2/RAD51C/RAD51D etc). The literature is mature regarding the benefits of RRBSO for proven BRCA1 and BRCA1 deleterious gene carriers. Risk reduction surgery is recommended for BRCA1 carriers at the age of 35-40 or after completion of childbearing. RRBSO for BRCA2 carries can be deferred to the age of 45, if the patient wishes. Studies regarding RRBSO for patients with other genetic alterations are currently in progress. All patients with an identifiable personal or family risk factors are recommended to have formal genetics consultation prior to proceeding with risk reducing surgery. Appropriate surgical intervention and specifics for pathology analysis of specimens (SEE-FIM) have been described.

Article References

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2. Risk Assessment, Genetic Counselling and Genetic Testing for BRCA Related Cancer: USPSTF Recommendation Statement / JAMA / Vol. 322, No. 7 / pgs 652-633 / August 20, 2019
3. Ovarian Cancer Risk After Salpingectomy: A Nationwide Population Based Study, JNCI / Volume 107, Issue No.2 / Feb 1,2015 / Falconer, Yin, Groenberg, Altman
4. The Fallopian Tube, "Precursor Escape": Narrowing the Knowledge Gap to the Origins of High Grade Serous Carcinoma. Gyn Onc / 152 Feb 2019 / pgs 426-433 / Soong, Crum et al.
5. College of American Pathologists (CAP) Protocol for the Examination of Specimens with Carcinoma of the Ovary. AJCC/UICC 7th Edition. Web posting (CAP.org). October 2009
6. National Comprehensive Cancer Network (NCCN) Genetic/Familial High Risk Assessment: Breast and Ovarian Cancer. NCCN.org (2020)

Brachytherapy for gynecologic malignancies

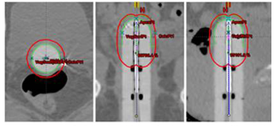
by | ANDREW NEUSCHATZ, MD, RADIATION ONCOLOGIST

Brachytherapy is a technique of placing radioactive sources on, in, or near a tumor. The root of the word, brachy, means short distance. This allows for high doses of radiotherapy to be delivered to a tumor with a rapid fall off, allowing dose to nearby structures to be minimized. Brachytherapy is an essential part of the treatment of multiple gynecologic malignancies, most prominently cervical and endometrial cancers. It can be used alone or in combination with external beam radiotherapy and is used both in the post-operative setting as well as part of definitive non-operative management.

Vaginal cylinder brachytherapy

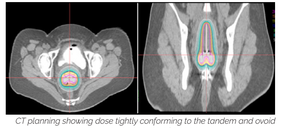
In 2018, cervical cancer was the 4th most common cancer in women worldwide with an estimated 570,000 cases. Incidence has declined in developed countries by over 70% thanks to screening, but in the developing world it remains the second leading cause of cancer death in women. For women with non-operative, locally advanced cervical cancer, the standard of care in the U.S. over recent decades has evolved from external beam radiotherapy, to external beam radiotherapy with brachytherapy, to external beam radiotherapy, brachytherapy, and concurrent chemotherapy. The primary goal of external beam radiotherapy in cervical cancer is to sterilize lymph nodes and microscopic disease and to shrink the primary tumor to allow it to be encompassed within the high dose area of brachytherapy. The brachytherapy is usually done towards the end of the external beam radiotherapy to allow for maximal shrinkage. In patients with an intact cervix, a tandem and ovoids are usually used, although other arrangements are available depending on anatomy. Sedation is used for patient comfort. The tandem is an angled thin metal tube placed through the dilated cervix into the uterus. The ovoids are shorter tubes and have space occupying ovoid inserts on the end, placed into the vaginal fornix against the cervix. Packed gauze is used to hold the applicators firmly in place. A CT based simulation, or planning session, is done with the applicators in place. That allows the treatment to be customized to the individual anatomy and tumor extent. The applicators have a hollow center and are attached to an after loader. This is a metal shielded machine with a small iridium-192 source at the end of a wire. This is robotically pushed into the hollow center of the applicator and sits at various positions for a few seconds to a few minutes in each location as determined by the plan. This is called high dose rate (HDR) brachytherapy, as opposed to low dose rate (LDR) brachytherapy, which can take many hours and is more rarely used in contemporary gynecologic practice. At the end of the procedure, the source is automatically withdrawn back into the brachytherapy unit and the applicators are removed from the patient. There is no radioactivity present once the source has been withdrawn and patients require no radiation safety precautions for discharge. Women go home shortly after. In a typical curative case, 4-5 insertions are done over 2-3 weeks. Side effects can include vaginal soreness, spotting, dysuria, and diarrhea. Long term vaginal scarring or narrowing is possible and can be avoided or minimized with the use of a vaginal dilator afterwards.

The use of brachytherapy as part of the treatment plan for locally advanced non-operative cervical cancer is critical. Brachytherapy is technically challenging, time consuming, and poorly reimbursed so many centers have tried to use increased doses of external beam to make up for a lack of brachytherapy, causing a decline in its use over past decades. Studies have shown women treated without brachytherapy as part of their definitive treatment plan have inferior survival, even with an increased external beam dose. In Arizona Oncology we have always emphasized the importance of brachytherapy and have known the improved outcomes merit the effort involved for patients and physicians alike. Patients, as well as primary care physicians and gynecologists need to be aware that in non-operative but curable cervical cancer, brachytherapy is essential to achieve the best possible cure rates. Both the Society for Gynecologic Oncology (SGO) as well as the American Society for Radiation Oncology (ASTRO) and the American Brachytherapy Society (ABS) agree that brachytherapy is "an integral component in the standard of care for patients receiving primary radiotherapy for cervical cancer."



Radiation dose tightly conforming to the shape of the cylinder.

Brachytherapy is also used commonly postoperatively in the adjuvant setting, particularly for high risk endometrial cancer. The most common location for postoperative recurrence in endometrial cancer is at the vaginal apex. Risk factors are not completely consistent between trials but generally include stage, including cervical involvement, grade, depth of invasion, lymphovascular space invasion, and older age. In patients thought to be at high risk for recurrence at the vaginal apex, postoperative brachytherapy is often recommended. This can be done alone, or with external beam radiotherapy in patients also at a high risk of pelvic or nodal recurrence, and occasionally with chemotherapy in patients with risk of distant disease as well.



CT planning showing dose tightly conforming to the tandem and ovoid apparatus with sparing of bladder, bowel, and rectum.

In women who have had a hysterectomy, brachytherapy is most commonly done with a vaginal cylinder. This is a plastic cylinder of various diameters with a hollow center. It is placed in the vagina and imaging is done to ensure good fit and individualized treatment planning. Typically, sedation is not required for vaginal cylinder placement. Once planning is complete, the high dose rate brachytherapy afterloader is attached to the cylinder and the iridium-192 source is robotically pushed into the hollow center. It will sit in various locations within the cylinder for a few minutes at a time. At the end, the source is robotically withdrawn into the shielded afterloader, the cylinder is removed, and the patient goes home. Vaginal cylinder brachytherapy is often done 3 times over 1-2 weeks. Side effects can include vaginal discharge, cramping, diarrhea, dysuria, and vaginal narrowing. The use of a vaginal dilator after vaginal cylinder brachytherapy is recommended. Multiple studies have shown high dose rate brachytherapy given with a vaginal cylinder after hysterectomy for high risk women can very effectively sterilize the vaginal apex and significantly reduce local recurrence risk with low toxicity.

In summary, brachytherapy is a technique of placing radiation on, in, or near tumors or high-risk areas that allow doses to surrounding normal structures to be minimized. Brachytherapy is an essential part of the contemporary standard of care both as definitive non-operative treatment for cervical cancer and as part of postoperative adjuvant care of high risk cervical and endometrial cancers. In Arizona Oncology, gynecologic oncologists work closely with their radiation oncology colleagues to determine the most appropriate treatment plan for each individual patient including the coordination of surgery, chemotherapy, external beam radiotherapy, and brachytherapy.

Arizona Oncology Clinical Trials and Research

Cervical Cancer Studies
First line with chemo and radiation (stage 1 and2 with + nodes, all stage 3)
Study of Durvalumab with Chemoradiotherapy for women with locally advanced cervical cancer (CALLA)
Location: Biltmore
NCT# NCT03830866

First line metastatic recurrent cancer
Safety and efficacy of Tisotumab Vedotin Monotherapy and in combination with other cancer agents in subjects with cervical cancer
Location: Biltmore
NCT# NCT03786081+A10.A41

Second line metastatic recurrent cancer
Phase2 study of Anti-PD-1 Independently or in combination with Anti-CTLA-4 in second line cervical cancer (RAPIDS)
Locations: Biltmore, Scottsdale(GYN), Tempe
Biomarkers: None required for enrollment
Prior lines of therapy: Either: 1 prior line of platinum-based therapy for cervical cancer, or metastatic, locally advanced, and/or unresectable squamous-cell carcinoma, adenosquamous carcinoma, or adenocarcinoma of cervix
NCT#NCT03894215

Ovarian Cancer Studies
First line advanced stage with large volume upper abdominal disease or high risk (residual disease after primary debulking, neoadjuvant or stage 4)
A Phase 3 Comparison of Platinum-based Therapy With TSR-042 and Niraparib Versus Standard of Care (SOC) Platinum-based Therapy as First-line Treatment of Stage III or IV Nonmucinous Epithelial Ovarian Cancer (FIRST)
Locations: Biltmore, Scottsdale (GYN), Tempe
Biomarker: None required for enrollment. HRR status required during screening.
Prior lines of therapy: None, this is first line treatment.
NCT#NCT03602859

Pending activation: A Study of Mirvetuximab Soravtansine in Advanced High-Grade Epithelial Ovarian, Primary Peritoneal, or Fallopian Tube Cancers With High Folate Receptor-Alpha Expression (SORAYA)
Prior lines of therapy: at least 1 but no more than 3 prior systemic lines of anticancer therapy, including at least one line of therapy containing bevacizumab
Biomarker: Folate Receptor Alpha (+)
Biltmore, Scottsdale (GYN), Tempe
NCT# NCT04296890

A Study of Mirvetuximab Soravtansine vs. Investigator's Choice of Chemotherapy in Platinum-Resistant, Advanced High-Grade Epithelial Ovarian, Primary Peritoneal, or Fallopian Tube Cancers With High Folate Receptor-Alpha Expression (MIRASOL)
Biomarker: Folate Receptor Alpha (+)
Locations: Biltmore, Deer Valley, Tempe
NCT# NCT04209855

Efficacy and Safety Study of AVB-S6-500 in Patients With Platinum-Resistant Recurrent Ovarian Cancer
Prior lines of therapy: At least one but no more than 3 therapy regimens, not including maintenance or hormonal therapy
Biomarker: None required for enrollment. At least AXL, pAXL, pAKT, and GAS6 will be evaluated during study.
Locations: Biltmore, Deer Valley, Tempe, Scottsdale (GYN)
NCT# NCT03639246

A Study of VB-111 With Paclitaxel vs Paclitaxel for Treatment of Recurrent Platinum-Resistant Ovarian Cancer (OVAL) (OVAL)
Prior lines of therapy:+ at least 1 line of platinum based therapy
Biomarker: If patient is known to carry a BRCA mutation – they may be enrolled only after failing a PARP inhibitor treatment, or being intolerant of, or ineligible for PARP therapy.
Location: Biltmore
ClinicalTrials.gov Identifier: NCT03398655

Please note: If you are unable to find a clinical trial that works for you, contact 888.972.CURE and ask for the Research Department.
Disclaimer: Studies may close promptly when target enrollment is met.