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COMIRB No: 26-0543
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Study Title: *Targeting immune modulation in high grade serous carcinoma: combined effects of chemotherapy and atorvastatin*

Key Information

You are being asked to be in a research study. Participation is voluntary. This form describes the study. A member of the research team will explain the study to you and answer all of your questions. Take your time to read the information below and ask questions about anything you don't understand before deciding whether or not to take part.

Purpose of the Study:

This study plans to learn more about how atorvastatin, a common medication for cholesterol, affects the immune system and high grade serous ovarian cancer in response to chemotherapy. The use of atorvastatin in this study is considered investigational.

You are being asked to be in this research study because you are seeking care for your stage III to IV high grade serous ovarian, peritoneal, or fallopian tube cancer.

Procedures:

If you join the study, you will receive the standard of care chemotherapy with carboplatin and paclitaxel for 3-4 cycles, then undergo interval debulking surgery, followed by another 2-3 cycles of chemotherapy.

In addition to the standard of care chemotherapy, half of the participants will also take atorvastatin daily by mouth.

We will use tissue from your biopsy and eventual surgery to look at changes in immune cells. You will be asked to take the study medication daily for the duration of your chemotherapy (six cycles) and surgery. You will not have any extra visits due to this study, but some additional blood tests will be added to your scheduled laboratory tests (blood work).

Your participation will last for approximately 12 months (6 months of treatment followed by 6 months of safety follow-up).

Risks:

Participation in this study involves risks, including the following:
For atorvastatin, the most common risks are muscle pain, liver toxicity, neuropathy, and decreased blood counts.

For platinum-based chemotherapy (e.g. carboplatin), the most common risks are myelosuppression, vomiting, nephrotoxicity, neurotoxicity, and ototoxicity.

For taxanes (e.g. paclitaxel), the most common risks include neuropathy, hypersensitivity reaction, and bone marrow suppression.

Benefits:

There is no guarantee that your health will improve if you join this study. This study may lead to information that could help patients and health care providers in the future.

Alternatives:

Routine care for your condition involves treatment with carboplatin, paclitaxel, and surgery. You do not have to participate in this study to receive treatment for your condition. Please discuss routine care with your doctor before deciding to participate in this study.

Detailed Description of the Study

Why is this study being done?

We are doing this study to learn more about the role that atorvastatin may play in the tumor immune microenvironment, specifically its effects on immune cells.

You are being asked to be in this research study because you have a diagnosis of stage III or IV high grade serous carcinoma.

Up to 40 people from your area will be in the study.
Up to 40 people around the country will be in the study.

What happens if I join this study?

If you join the study, you will be asked to sign this consent form. You will be given a copy to keep and the original form will be kept at the clinic. You can withdraw from the study at any time and without giving a reason. This will not affect the standard medical care you receive.

Once you are determined to participate, there are three major parts to the study:

1. Screening Phase
2. Treatment Cycles
3. Post-Treatment

The screening phase happens at least one day before the first day of treatment, but it can be as many as 28 days before the first day of treatment.

For the treatment phase, you will be randomized to be on Arm 1 (Standard of Care Only) or Arm 2 (Treatment Arm of Standard of Care with atorvastatin). There is a 50/50 chance (like the flip of a coin) that you will be placed in either arm.

The treatment phase includes “cycles” that are each 21 days (three weeks) or 28 days (4 weeks) long. You will be given treatment for three cycles. Next, you will have an interval surgery. Following surgery, you will have three to four more cycles of treatment. If you are randomized to be in Arm 2, then you will also be taking the study medication, atorvastatin.

The post-treatment phase includes end of treatment and safety follow-up reviews. We will also follow your survival for up to six months.

Study Procedures

Some procedures you receive while taking part in this study are “standard of care” procedures for treatment of your disease. This means you would be receiving these procedures regardless of whether or not you were part of this research study. If you have had some of these procedures recently, they may not need to be repeated.

Some procedures you receive while taking part in this study are “research” procedures and are required only for this research study. All procedures performed for research are marked below.

- **Informed Consent *(research)***
  This informed consent form will be discussed with you and you will be given a copy of this document. If you join the study, you will be asked to sign this consent form before you receive any study related tests or procedures.

- **Medical and Cancer History**
  Before you start the study, we will record your date of birth, race, ethnicity, and complete medical history. This medical history will look at the background and history of your cancer and any treatments you have received for your disease.

- **Tumor Biopsy**
  An image-guided biopsy will be performed, where a needle is inserted into the affected area using imaging such as computed tomography , ultrasound, or magnetic resonance imaging to collect cells or tissue from an organ, lymph node, or suspected tumor mass. The doctor will use the imaging to guide the

needle into the area and collect a small piece of tissue. The biopsy will be used to diagnose your cancer, and is not a research procedure, but samples from this biopsy will be used for research purposes as well.

- **Current Medications**
  Your study doctor will let you know which drugs you can and cannot take while taking part in this study. You will need to check with the study doctor before taking any new medications, including over the counter drugs and herbal supplements. From the time you first receive the study drugs through 30 days after the last dose, we will record medications you may be taking.

- **Review of Side Effects *(research)***
  Some risks have been identified because of the disease process or through use of the study drugs. These are commonly called side effects and will be followed very closely by your doctor and the study staff. More information about these will be provided in the risk section of this consent form.

- **Physical Examination**
  A physical examination will be completed as part of your standard of care at screening and throughout the duration of the study. After you join the study, we will assess if the study drugs are affecting your body functions including lungs, heart, abdomen, extremities, skin, head (eyes, ears, nose, hair, etc.) and your neurological function.

- **Performance Status**
  We will assess how well you are performing your daily activities.

- **Vital Signs, Height & Weight**
  We will collect your vital signs including blood pressure, pulse, respiratory rate, body temperature and height and weight per standard of care.

- **Blood Samples**
  These tests are sometimes called safety labs so the study doctor can be sure it is safe for you to take part in this study and to be given the study drugs.
    - Pregnancy test: Women who are able to become pregnant will be given either a urine or a blood pregnancy test. A positive pregnancy test prior to being given the study drugs will exclude you from starting or continuing to take part in the study.
    - Complete blood count (CBC) with Differential
    - Comprehensive metabolic panel (CMP)
    - Lipid profile (including total cholesterol, LDL, HDL, triglycerides)

- **Study Drug Administration *(research)***
  In addition to your standard of care treatment, you may be taking 40mg atorvastatin daily while participating in this research study.

- **Tumor Imaging (CT)**
  Computed Tomography (CT) scans use x-rays to make detailed pictures of parts of the body and the structures inside the body.

- **Protein Cancer Antigen Test (CA 125 test)**
  Test that measures the amount of protein caner antigen 125 in the blood to monitor your cancer condition or treatment.

- **Survival Status *(research)***

The time points when these study procedures will take place are outlined below in the *Table of Study Procedures.*

Table of Procedures

Study Visits	**Screening**	**Cycles 1-3 or Cycles 1-4**	**Interval Surgery**	**Cycle 4 or Cycles 5-6**	**Post-therapy follow-up**	**Survival follow-up**
	Day -28 to Day 0	*Day 0- Day 63*	*Day 63 -Day 107*	*Day 107 – 170*	*Every 90 Days (+/- 7 days)*	*12 months (+/- 30 days)*
Procedures						
Informed consent	X					
Confirm eligibility (inclusion/exclusion criteria)	X					
Medical History	X					
Tumor Collection	X (core needle biopsy)		X (surgery)			
Concomitant Medications and Procedures	X	X	X	X	X	
Toxicity/AE assessment		X		X	X	
Physical Exam	X	X	X	X	X	
ECOG performance status	X	X	X	X	X	

Height/weight	X	X	X	X	X	
Vital Signs	X	X	X	X	X	
CBC/CMP	X	X	X	X	X	
Lipid profile	X		X			
Serum pregnancy	As needed	As needed	As needed	As needed	As needed	
Study treatment provided		X		X		
Medication adherence and modification	X	X		X		
CT imaging chest/abdomen/pelvis	X		X		As needed	
Protein Cancer Antigen test (CA 125 test)	X	X	X	X	X	X
Survival status						X*
*Conducted by phone or medical record review on annual basis for survival data.						

If you join the study, you will participate in the following visits:

Screening: 0-28 days prior to treatment:

After it has been confirmed you are eligible to participate and you have signed this informed consent form, the following procedures will be performed as part of this study:

- We will ask you information about your medical history, medications you are taking, past medical procedures and your performance status
- We will take your vital signs including weight, temperature, pulse, blood pressure, and respiratory rate
- If you have not already had a biopsy to diagnose your cancer, you will you will undergo a biopsy with interventional radiology, a procedure under sedation where they use imaging and a needle to get a sample of your tissue. Alternatively, if they are unable to get adequate tissue on biopsy you may undergo a laparoscopic biopsy, a procedure where you would go to the operating room and using small incisions obtain a sample of tissue to diagnose your cancer.
- You will be randomized to be on Arm 1 (Standard of Care Only) or Arm 2 (Treatment Arm of Standard of Care with atorvastatin). There is a 50/50 chance (like the flip of a coin) that you will be placed in either arm.

The following activities will also take place at this visit, though they are part of your standard or usual treatment and would take place even if you did not participate in research

- A physical examination including heart, lung, and abdomen exam
- We will draw a small amount of blood (2-3 tablespoons)

- We will perform a CT scan of your chest, abdomen, and pelvic area. CT is a way of taking detailed pictures inside your body by using X rays. X rays are a type of radiation

Treatment Visits:

These visits will include

- Serum pregnancy test for patients of childbearing potential/not underwent surgical menopause
- We will evaluate your performance status
- We will dispense atorvastatin if you are in the treatment arm and ask about this medication and any side effects.
- We will ask you about medications you are taking, adverse events your are experiencing, past medical procedures,

As part of your usual or standard of care, the following procedures will also be performed

- We will draw a small amount of blood (2-3 tablespoons)
- Physical examination
- We will record your weight, vital signs (temperature, pulse, blood pressure, respiratory rate)
- We will administer you standard of care chemotherapy every 3 weeks with a platinum-based agent and a taxane for a total of 6-7 cycles
- CT imaging of the chest abdomen and pelvis (to be conducted after cycle 3 and at end of treatment.

Interval Surgery

After 3-4 cycles, you will then undergo interval surgery, a surgery where your oncologist will remove all visible tumor, possibly including the uterus, cervix. Fallopian tubes, ovaries, omentum, and all other sites of disease. In this surgery some tumor samples and blood samples will be collected for the study as well as some go to pathology for review.

Post Therapy Follow-up

After you have completed your chemotherapy you will follow up as standard with your doctor

- We will ask you about medications you are taking, adverse events you are experiencing, past medical procedures
- We will record your performance status

As part of your usual or standard care the following procedures will also be performed

- A physical examination
- We will record your weight, vital signs (temperature, pulse, blood pressure, respiratory rate)
- We will draw a small amount of blood (2-3 tablespoons)

- CT imaging of the chest abdomen and pelvis (at the discretion of your provider based on rising CA-125 levels or symptoms)

Survival Follow-up:
Once you complete the end of treatment visit you will be contacted annually after your last dose of the study drug. This may occur via telephone or at a clinic visit.

What are the possible discomforts or risks?

As with any study drug, side effects may occur when taking the study drug. While taking part in this study, and being treated with the study drug, you will be watched carefully for any side effects. Some side effects may go away after you stop taking the study drug. Some side effects can be long-lasting and may never go away.

You should talk to your study doctor about any side effects or discomfort you may have. The study doctor may give you some medicine that will help with some side effects. The study doctor may also interrupt or discontinue the study drug.

You will be notified by your study doctor of any new side effects seen in other patients that occur during the time you are on the study. This may affect you wanting to continue in this research study.

Based on animal studies and/or other studies with similar types of drugs, side effects or discomforts you may experience while in this study include:
Risks of Study Drugs

Atorvastatin:

Most common:

- Nasal congestion, sore throat, runny nose
- Urinary tract infection
- Muscle spasms
- Diarrhea
- Nausea
- Throat pain
- Muscle and joint pain
- Pain in extremity
- Upset stomach
- Pain, especially in the bones, muscles, ligaments, tendons, and nerves
- Trouble sleeping

Less likely:

- Rapid muscle breakdown (rhabdomyolysis), leading to kidney dysfunction that may cause **death**
- Autoimmune disease that causes muscle fiber death (immune-mediated necrotizing myopathy)
- Liver dysfunction (non-fatal)
- Increased blood sugar

Platinum chemo therapy:
Most common:

- Low blood counts
- Nausea and Vomiting
- Painful inflammation of mucous membranes lining the digestive tract (mucositis)
- Pain
- Loss of hair (alopecia)

Less likely:

- Hypersensitivity reaction
- Damage to peripheral nerves, causing numbness/tingling/pain usually in toes and fingers (peripheral neuropathy)
- Kidney dysfunction
- Hearing loss

Taxane chemotherapy:
Most common:

- Low blood counts
- Damage to peripheral nerves, causing numbness/tingling/pain usually in toes and fingers (peripheral neuropathy)
- Swelling caused by excess fluid trapped in body tissues (edema)
- Low blood pressure
- Diarrhea
- Nausea and vomiting
- Hair loss (alopecia)
- Hypersensitivity reaction, severe hypersensitivity reaction less likely

Less likely:

- Abnormal heart rhythm (cardiac arrythmia)
- Brain dysfunction/damage/disease (encephalopathy)
- Seizure

Risks of Having an IV Inserted in Your Vein

IV injections may cause slight discomfort when the needle is inserted into the vein. It may cause momentary discomfort during the puncture, light-headedness, fainting, soreness and/or bruising for several days. In very rare circumstances, either bleeding or infection can develop at the needle puncture site.

Risks of Blood draw: In this study, we will need to get about 2-3 tablespoons of blood from you. We will get blood by putting a needle into one of your veins and letting the blood flow into a glass tube. You may feel some pain when the needle goes into your vein. A day or two later, you may have a small bruise under the skin.

Risks of CT Scan: As part of this study we will perform CT scans of your chest, abdomen, and pelvis. CT is a way of taking detailed pictures inside your body by using X-rays. X-rays are a type of radiation.

You get some radiation from your environment. You get radiation from bricks and concrete, from some foods, and from radon gas, which is an invisible gas that seeps out of the ground. The amount of radiation that this CT scan will deliver to your body (give you) is about the same as you would get from living in your environment 5 years.

Risks of Image-Guided Biopsy: As part of your standard or usual treatment you will undergo an imaging guided biopsy. Having biopsies performed may cause pain, bruising, bleeding, redness, low blood pressure, swelling, and/or infection at the site of the biopsies. An allergic reaction to the anesthetic may occur. A scar may form at the biopsy site.

Risks of Having an Magnetic Resonance Image (if used for image-guided biopsy)

Magnetic Resonance Images are taken using a machine that uses powerful magnetic waves to take pictures inside the body. The waves themselves are not harmful, but they can cause metal to heat up and electronics to stop working. You should NOT have this procedure performed if you have metal or electronic devices inside your body. Heart pacemakers and insulin pumps are examples of electronic devices.

Part or all of the body will be passed into a long, narrow tube scanner, which is open at both ends, for the imaging.

Interval debulking surgery: as part of your standard or usual treatment you will undergo interval debulking surgery including removal of the uterus, fallopian tubes, ovaries, omentum, and any other sites of tumor that are present. Risks and discomforts of surgery include pain, bleeding, injury to bowel, bladder, nerves, blood vessels. Your doctor will discuss the detailed surgical plan and risks and sign a separate consent form when you are scheduled for surgery.

The study may include risks that are unknown at this time. If there are any significant new findings during the study that may affect whether you want to continue to take part, you will be told about them.

Risk of Confidentiality/Privacy Loss: If you join the study, there may be some loss of privacy. We will do our best to make sure information about you is kept confidential but we cannot guarantee total privacy.

Reproductive Risks: The use of atorvastatin can cause fetal harm. If you are of child-bearing potential you must agree to adhere to the contraception requirements outlined by your study doctor while participating in the study.

Other Risks

The combination of the study drug with chemotherapy may involve risks which are currently unforeseeable at this time.

What are the possible benefits of the study?

This study is designed for the researcher to learn more about high grade serous carcinoma However, there is no guarantee that your health will improve if you join this study.

Are there alternative treatments?

There may be other ways of treating your condition, including chemotherapy alone. You could also choose to get no treatment at all.

You should talk to your doctor about your choices. Make sure you understand all of your choices before you decide to take part in this study.

How will my information be used?

The information collected for this study will be studied for the purposes described above. We intend to publish and share the results of this study. Your identity will be kept private when we publish and share our results. We will use your information until we close the study or until you decide to stop participating.

We may share study data in public or restricted data banks so that the data may be used by other researchers. Your name and other information that could directly identify you will not be sent to data banks without your permission. Even though information that directly identifies you will not be shared, we cannot guarantee that no one will ever be able to use this information to identify you. Broadly sharing data in this way may involve risks to you or others that are unknown at this time.

Study data may be used for future research or distributed to other researchers for future study without additional consent if the information that identifies you is removed. Future research could be about your condition or other related medical conditions. Other researchers may work for other universities, the government, or private industry.

We may contact you in the future to ask you to participate in additional research. You are free to say no to any future requests.

Who is paying for this study?

Support for this research is provided by the university.

Will I be paid for being in the study?

You will not be paid to be in the study.

Will I have to pay for anything?

You and your insurance will have to pay for all of the visits, procedures and care described in this consent form. You will be responsible for co-payments and deductibles that are standard for your insurance coverage.

The study drug will be provided at no cost to you. However, you and your insurance will be billed for preparing and administering the study drug.

Questions about costs that will or will not be covered by your insurance should be addressed to the customer care team for UCHealth Billing, 1.866.429.6045, or CU Medicine Group Billing, 303.493.7700, who are available Monday-Friday, 8 a.m. to 5 p.m.

Is my participation voluntary?

Joining the study is voluntary. If you choose to take part, you have the right to stop at any time. If you refuse or decide to withdraw later, you will not lose any benefits or rights to which you are entitled.

Can I be removed from this study?

The study doctor may remove you from the study without your permission if you experience unacceptable side effects, if you can't complete study procedures, or for any other reason. Also, the sponsor may stop the study at any time.

What happens if I am injured or hurt during the study?

If you have an injury while you are in this study, you should call Dr. Marjon immediately. Her phone number is 303-724-2066. In the event of an illness or injury resulting from your participation in this study, you should seek appropriate medical care. However, you and/or your insurance company will have to pay for that care.

Who do I call if I have questions?

The researcher conducting this study is Dr. Marjon. You may ask any questions you have now. If you have questions, concerns, or complaints later, you may call Dr. Marjon at 303-724-2066.

You may have questions about your rights as someone in this study. You can call Dr. Marjon with questions. You can also contact the responsible Institutional Review Board (COMIRB). You can call them at 303-724-1055 or email them at COMIRB@ucdenver.edu.

A description of this clinical trial will be available on http://www.clinicaltrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Who will see my research information?

The University of Colorado Denver | Anschutz Medical Campus (the University) and its affiliated health systems have rules to protect information about you. Federal and state laws including the Health Insurance Portability and Accountability Act (HIPAA) also protect your privacy. This part of the consent form tells you what information about you may be collected in this study and who might see or use it.

The institutions involved in this study include:

- University of Colorado Denver | Anschutz Medical Campus
- University of Colorado Health (UCHealth)

We cannot do this study without your permission to see, use and give out your information. You do not have to give us this permission. If you do not, then you may not join this study.

We will see, use and disclose your information only as described in this form and our Notice of Privacy Practices; however, people outside the University and its affiliate hospitals may not be covered by this obligation.

We will do everything we can to maintain the confidentiality of your personal information but confidentiality cannot be guaranteed.

The use and disclosure of your information has no time limit. You can cancel your permission to use and disclose your information at any time by writing to the study's Principal Investigator (PI), at the name and address listed below. If you do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in this study.

Nicole Marjon MD PhD
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Academic Office 1; Mail Stop B198-4
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Both the research records that identify you and the consent form signed by you may be looked at by others who have a legal right to see that information, such as:

- Federal offices such as the Food and Drug Administration (FDA) and the Office of Human Research Protections (OHRP) that protect research subjects like you.
- The Institutional Review Board that is responsible for overseeing this research
- The study doctor and the rest of the study team.
- Officials at the institution where the research is conducted and officials at other institutions involved in this study who are in charge of making sure that we follow all of the rules for research

You have the right to request access to your personal health information from the Investigator.

Information about you that will be seen, collected, used and disclosed in this study:

- Name and Demographic Information (age, sex, ethnicity, address, phone number, etc.)
- Portions of your previous and current Medical Records that are relevant to this study, including but not limited to Diagnosis(es), History and Physical, laboratory or tissue studies, radiology studies, procedure results
- Research Visit and Research Test records
- Tissue samples and the information with the samples.

What happens to Samples and Information that are collected in this study?

Scientists at the University and the health systems involved in this study work to find the causes and cures of disease. The samples and information collected from you during this study are important to this study and future research. If you join this study:

- The samples and information given by you to the investigators for this research no longer belong to you.
- Both the investigators and any sponsor of this research may study your samples and information collected from you.
- If the samples and information are in a form that identifies you, the University or the health systems involved in this study may use them for future research only with your consent or Institutional Review Board (IRB) approval.
- Any product or idea created by the researchers working on this study will not belong to you.
- There is no plan for you to receive any financial benefit from the creation, use or sale of such a product or idea.

Agreement to be in this study and use my samples and information

I have read this paper about the study or it was read to me. I understand the possible risks and benefits of this study. I understand and authorize the access, use and disclosure of my information as stated in this form. I know that being in this study is voluntary. I choose to be in this study. I will get a signed and dated copy of this consent form.

_____ _____
Signature of participant Date

_____
Printed name of participant

_____ _____
Signature of person obtaining consent Date

_____
Printed name of person obtaining consent

_____ _____
Signature of witness to the consent process Date
(A witness is only necessary for enrollment of participants who do not speak English when a short form consent process is used, or for enrollment of participants who are blind or illiterate.)

_____
Printed name of witness