Combined treatment of CLR 131 with Radiation for Head and Neck Cancer

10/6/2022

NCT04105543

University of Wisconsin-Madison
Consent to Participate in Research
and
Authorization to Use Protected Health Information for Research

Study Title for Participants: Combined treatment of CLR 131 with Radiation for Head and Neck Cancer

Formal Study Title: Therapeutic Combination of CLR 131 with External Beam Radiation in Head and Neck Cancer

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Where Lead Researchers work: University of Wisconsin Carbone Cancer Center
Where the Co-Investigator works: University of Wisconsin Cancer Center Johnson Creek

_____ _____
Participant name Medical Record Number

Invitation

We invite you to take part in a research study investigating how a small cancer-targeting molecule called CLR 131 combined with radiation therapy impacts head and neck cancers. We are inviting you because you have been diagnosed with head and neck cancer that has previously been treated and has returned after standard therapy.

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The purpose of this consent and authorization form is to give you the information you need to decide whether to be in the study. It also explains how health information will be used for this study and requests your authorization (permission) to use your health information. Ask questions about anything in this form that is not clear. If you want to talk to your family and friends before making your decision, you can. Once we have answered all your questions, you can decide if you want to be in the study. This process is called "informed consent."

Important things to know about any research study:

Taking part in research is voluntary. You can choose not to be in this study, or stop at any time.

If you decide not to be in this study, your choice will not affect your healthcare or any services you receive. There will be no penalty to you. You will not lose medical care or any legal rights.

You don't have to be in this study to get care for your health condition.

Study Summary

What is this study about?

We want to find out if CLR 131 combined with radiation therapy (external beam radiation therapy or EBRT) is safe to use for recurrent head and neck cancer, to find a safe dose to use in future studies, and to find out what side effects CLR 131 has in people with recurrent head and neck cancer. CLR 131 is an investigational drug. This means that the US Food and Drug Administration (FDA) has not approved CLR 131 for the treatment of recurrent head and neck cancer, and CLR 131 can only be given in a research study.

What will happen during the study?

You will have screening tests to find out if you can be in the study and fill out questionnaires about how you are feeling. You will start taking potassium iodide drops to help reduce radiation exposure to your thyroid gland.

Then you will receive an initial test dose of CLR 131. CLR 131 is given through an IV needle into a vein in your arm. 3 days after the injection, you will have a SPECT/CT scan. If the CLR 131 is not absorbed in the tumor imaging will be repeated approximately 4 days later (day 7-8 after injection). If the scan shows that your tumor absorbed the CLR 131, you can continue into the study treatment period. Additionally, six subjects who's tumor did not "absorb" the test will continue on to the the study treatment. Your physician will discuss

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this with you prior to proceeding to the therapeutic doses.

There are two parts to study treatment:

- 2 doses of CLR 131, about 1 week apart. CLR 131 is a radioactive agent. You may need to stay overnight in a lead-shielded room for up to 3 days for your safety and to protect others from the radiation you emit. You will keep taking potassium iodide every day until 2 weeks after the last dose of CLR 131.
- External beam radiation therapy (EBRT). The EBRT will begin about 2-3 weeks after the last CLR 131 treatment. Your treating physician will tell you how many EBRT treatments you will need.

While you are receiving study treatment, you will have blood tests, physical exams, an EKG, and imaging scans.

How much time will I spend on the study?

Each appointment could last up to 90 minutes depending on the procedures. You will actively participate in this study for about 27 months total.

Could taking part in the study help me?

Being in this study may lessen the side effects of standard full dose radiation treatments. The study treatment may work better than standard care for your condition, but we cannot promise this will happen. The study treatment might not work at all, or it might have bad side effects. Even if the study does not help you directly, your participation in this study may help other people in the future by helping us learn more about how CLR 131 and EBRT work together.

What are the main risks of taking part in the study?

All treatments have possible side effects. We will watch for side effects during study treatment and do what we can to relieve them. But you should know that side effects can be serious, even life-threatening, or may not go away.

The most common side effects of CLR 131 are upset stomach, vomiting (throwing up), feeling tired, increasing your chances for getting an infection.

The most common side effects of the EBRT include: mucositis, difficulty swallowing, dry mouth, change in taste and smell, reduced saliva production, hoarseness, radiation dermatitis, ear pain/infection, hearing loss, fatigue, weight loss, dehydration, hair loss, tooth decay, and decreased thyroid function.

The consent form explains the possible side effects in more detail. There may be other side effects we don't know about yet.

How is research different from health care?

When you go to a health provider for care, the provider focuses on how to help you as an individual. When you take part in a study, you are helping to answer a research question, like how safe or effective a treatment is, or what dose to use. Treatment is based on a study plan, not on you as an individual.

Do I have other treatment options?

Yes. Talk to your doctor about your other options.

Questions about the study?
Contact the research team:
608-263-8500

Emergency contact: 608-263-8500

Questions about your rights as a research participant? Have a complaint about the research?
Contact University of Wisconsin Hospital and Clinics Patient Relations Representatives at 608-263-8009.

More information about this study

Why are researchers doing this study?

The purpose of this research study is to determine the safety of the combination of CLR 131 with external beam radiation therapy. CLR 131 is an investigational radioactive drug. The word “investigational” means that CLR 131 is not approved by the U.S. Food and Drug Administration (FDA) and is available for research use only. CLR 131 is delivered through an intravenous infusion (IV) in your arm.

We are doing this research because when cancer in the head and neck area recurs or returns it is challenging to adequately treat. Standard external beam radiation therapy (EBRT) given in 30-35 treatments (60-70 Gy) has a high risk of causing long-term injury to the normal tissue around the tumor. The injury to the normal tissue is caused by the radiation passing through the tissue to reach the tumor. CLR 131 is a small radioactive cancer-targeting molecule called a PDC (phospholipid ether drug conjugate). The goal of targeted radiotherapy is to deliver effective doses of radiation directly to the tumor that can destroy tumor tissue from inside the tumor. Researchers hope that combining CLR 131 with the EBRT as a treatment could reduce the amount of external radiation needed to treat the tumor, thus reducing long-term injury to surrounding tissue.

This study is being done at the University of Wisconsin-Madison (UW-Madison). Up to 12 people overall will participate in this study at UW-Madison.

Funding for this study is provided by University of Wisconsin Comprehensive Cancer Center and Cellectar, the company that makes CLR 131, is providing CLR 131 for this study.

What will happen in this study?

Your doctors have determined that you need additional therapy to treat your cancer as it has started to grow back. Your physicians have recommended radiation therapy to treat your tumor.

There are two parts in this study, a dose escalation part and a dose expansion part. Your doctor will tell you which part you are in.

In the dose escalation part of this study, different people will get different doses of the study drug CLR 131.

There are 3 dose levels in this study. The first 4 people will start at middle dose level. If the drug does not cause serious side effects, the next group of people in the study will get the next higher dose. If the drug appears to cause serious side effects, the next subjects may get a lower dose or stay at the same dose level as the initial 4 subjects. Once we have determined the "best" dose level to use, all future subjects will be treated at that dose level.

In the dose expansion part of this study, the highest dose with manageable side effects will be given to participants once the best dose rate is found from the dose escalation. This will help study doctors better understand the side effects that may happen with this drug.

This study involves a screening period, treatment period, and a follow up period.

If you decide to participate and are determined to be eligible, you may have 12-15 additional research appointments beyond the standard of care radiation oncology appointments.

The Screening Period is to confirm that you can take part in the study. After you provide your consent to participate, your study doctor will arrange for you to have the following exams, tests or procedures, some of which you may already have had done:

Imaging of your neck and chest, lab work (about 1-2 tablespoons of your blood)

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and appointments with a radiation oncologist and a medical oncologist. These appointments will occur regardless of study participation to help determine your treatment options.

Pregnancy test if you are a women of child bearing potential (standard of care)

EKG (electrocardiogram – a test that measures the electrical activity of the hearbeat) (research)

Swallow function assessment (modified barium swallow). The modified barium swallow will take approximately 35 minutes: (standard of care)

Oral profile exam. The oral profile exam will measure saliva and swallow-related features in your mouth. The oral profile exam will take approximately 15-20 minutes (research procedure).

Oral swab and saliva collection and questionnaires regarding your quality of life and ability to carry out activities of daily living. You may skip any question on the questionnaires you do not wish to answer. The oral swab, saliva collection and completion of the questionnaires should take about 45 minutes (research procedure).

Another important part of screening is testing to see if your tumor absorbs CLR 131.

All participants will receive a test dose of the CLR 131 to ensure that the tumor absorbs the CLR 131. The CLR 131 will be given through a vein (intravenously) in your arm. You will need to remain in the clinic for 1 hr after the infusion. The whole appointment should last approximately 1.5 hrs. (research procedure)

We will take images (take pictures of your neck) approximately 3 days after the CLR 131 injection to see if the tumor absorbed the CLR 131. Images are acquired in the nuclear medicine department using single-photon emission computed tomography/computed tomography (SPECT/CT). SPECT/CT provides a 3D image to help determine if the CLR 131 has been absorbed in the cancer. If the CLR 131 is not absorbed in the tumor imaging will be repeated approximately 4 days later (day 7-8 after injection). If your tumor shows absorption of the CLR 131 you will continue on to the therapeutic infusions.

Six participants who don’t show absorption of the CLR 131 will be allowed to continue on to the therapeutic doses of the CLR 131, because we don’t know if the test dose and imaging can adequately predict how a patient may respond to

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this therapy. If your imaging doesn't show CLR 131 absorption, your physician will discuss with you the possibility of continuing on to the therapeutic portion of the study.

Imaging should take approximately 90 minutes. (research procedure)

Before the test infusion of CLR 131, you will start a medication (potassium iodide drops) to help reduce the radiation exposure to the thyroid gland. This medicine must be taken by mouth within 24 hours before your test dose of CLR 131 and will continue for 14 days after the last dose of CLR 131. Your doctor or the study team will tell you how to take this medication. (research procedure)

During the Treatment Period you will receive 2 treatment doses of CLR 131 followed by external beam radiation therapy (EBRT) and other exams, tests or procedures as follows:

CLR 131, investigational agent, injection over approximately 30 minutes on day 1 of the study followed by a second administration of CLR 131 on day 8. (research procedure)

You will have an IV inserted into one arm.
The study drug will be injected in one arm.
Since CLR 131 is a radioactive agent, you will be exposed to more radiation than normal. It is possible that you could expose others (like family or caregivers) to radiation because the radiation from the drug can linger in the body and take time to clear out. Depending on the dose of the study drug, you may need to stay overnight at the University of Wisconsin in a lead-shielded room because you are considered radioactive. You may be asked to stay in this lead-shielded room for approximately 1-3 days to maintain your safety and the safety of others. Study staff will discuss with you the likelihood of a hospitalization for observation based on the calculated absorption of the CLR 131.

After the study drug is injected, you will have the following procedures:
Your vital signs will be monitored for 1 hour after the infusion.
You will be asked about any adverse experiences you have had.

Blood tests will be drawn weekly for 12 weeks starting with the first treatment dose of CLR 131 to monitor for side-effects of the CLR 131 (about 1-2 tablespoons of your blood). (standard of care after administration of CLR 131)

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Pregnancy test if you are a women of child bearing potential (standard of care prior to each CLR 131 dose administration)

4 sets of SPECT/CT images will be obtained once at each of the following timepoints after the first CLR 131 injection: day 2, day 3, days 4-6 and day 7-8. Information obtained from the scans will allow the study investigators to determine the number of EBRT treatments that will be needed to complete your cancer treatment. Each set of images will take approximately 1 hr. (research procedure)

You will continue taking potassium iodide daily for thyroid protection until 14 days after the last CLR 131 infusion. (research procedure)

At some point prior to the first CLR 131 infusion, a planning CT will be obtained in radiation oncology to plan EBRT treatments. The planning CT will take approximately 30 minutes. (standard of care)

EBRT will begin approximately 1-3 weeks after the 2nd CLR 131 infusion. The exact number of EBRT treatments you will receive is based on how much CLR 131 was absorbed in your tumor. Your treating physician will tell you how many EBRT treatments you will receive. Each radiation treatment will take approximately 30 minutes. EBRT is called external beam radiation and does not stay in the body after treatment. (standard of care)

EKG on the first day of EBRT treatment (standard of care)

Evaluation of side-effects of CLR 131 and radiation will occur weekly once EBRT begins and will continue through the end of EBRT. (standard of care)

1 month after the first CLR 131 infusion you will see your physician for an exam to make sure you have recovered from the side-effects of the CLR 131 treatment. This appointment will take less then 1 hr (research procedure) and will occur on the same day as an EBRT treatment.

Follow-up period – After completion of EBRT you will be seen at the standard of care timepoints of 3, 6, 12 and 24 months post EBRT.

3 Month post EBRT visit (the entire visit could take up to 2 hours)

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Physical exam (standard of care)
Blood tests (approximately 1-2 tablespoons of your blood will be taken) (standard of care)
Swallow function assessment (modified barium swallow). Each appointment will take approximately 35 minutes: (standard of care)
Evaluation of treatment side effects (standard of care)
Disease assessment by CT, MR, or PET-MR or any combination of these standard of care imaging studies (standard of care)
Oral swab and saliva collection and questionnaires regarding your quality of life and ability to carry out activities of daily living. You may skip any question on the questionnaires you do not wish to answer. The saliva collection and completion of the questionnaires should take about 45 minutes. (research procedure)
Oral profile exam. The oral profile exam will involve measuring other saliva and swallow-related features in your mouth. Each appointment will take approximately 15-20 minutes (research procedure).

6 Month post EBRT visit

Physical exam done (standard of care)
Blood tests (approximately 1-2 tablespoons of your blood will be taken) (standard of care)
Swallow function assessment (modified barium swallow exam). Each appointment will take approximately 35 minutes. (standard of care)
Evaluation of treatment side effects (standard of care)
Oral swab and saliva collection and questionnaires regarding your quality of life and ability to carry out activities of daily living. You may skip any question on the questionnaires you do not wish to answer. The saliva collection and completion of the questionnaires should take about 45 minutes. (research procedure)
Oral profile exam. The oral profile exam will involve measuring other saliva and swallow-related features in your mouth. Each appointment will take approximately 15-20 minutes (research procedure)

12 Month post EBRT visit

Physical exam done (standard of care)
Blood tests (approximately 1-2 tablespoons of your blood will be taken) (standard of care)
Evaluation of treatment side effects (standard of care)
Disease assessment by CT, MRI, PET or any combination of these standard of care imaging studies (standard of care)

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Oral swab and saliva collection and questionnaires regarding your quality of life and ability to carry out activities of daily living. You may skip any question on the questionnaires you do not wish to answer. The saliva collection and completion of the questionnaires should take about 45 minutes. (research procedure)

24 Month Post EBRT visit

Physical exam done (standard of care)

Blood tests (approximately 1-2 tablespoons of your blood will be taken) (standard of care)

Evaluation of treatment side effects (standard of care)

Disease assessment by CT, MRI, PET or any combination of these standard of care imaging studies (standard of care)

Protected health information (PHI) used in this study

Protected health information, also called PHI, is information about your physical or mental health that includes your name or other information that can identify you, like your date of birth or medical record number. To do this study, we will use the following kinds of PHI:

Results of tests or procedures done as part of the study

Things you tell the researchers about your health

Information currently in your medical records as well as information added to your medical records during the course of this study. This information could include your medical history; your diagnosis; lab test results, X-rays, MRIs, CTs or other kinds of medical imaging; billing records. We will get this information from your health care providers such as UW Health.

How long will I be in this study?

You will actively participate in this study for about 27 months (through the 24 month post completion of EBRT visit).

The researchers may take you out of the study, even if you want to continue, if

- your health changes and the study is no longer in your best interest
- you do not follow the study rules or no longer meet the requirements to be in the study
- the study is stopped by the sponsor or researchers

How is being in this study different from my regular health care?

There is no single standard treatment for recurrent head and neck cancer. As part of their regular health care, people might have chemoradiation therapy, or chemotherapy, or no treatment at all. Your physicians are recommending you receive external beam radiation (EBRT) to treat your recurrent tumor.

If you take part in this study, the main difference between your regular care and the study is that you will receive infusions of the radioisotope CLR 131 in addition to EBRT, and the dose of EBRT you receive will be lower than for standard radiation therapy. We hope that the radiation delivered to your tumor from the CLR 131 will lower your EBRT doses enough to lessen the normal EBRT side effects.

Do I have to be in the study? What if I say "yes" now and change my mind later?

No, you do not have to be in this study. Taking part in research is voluntary. This means that you decide if you want to be in the study. If you decide now to take part, you can choose to leave the study at any time.

If you decide to be in the study, the researchers will tell you about new information or changes in the study that may affect your willingness to continue in the study.

Let the researchers know if you choose to leave the study. We will tell you how to leave the study safely.

If you decide not to take part in the study, or if you choose to leave the study, your choice will not affect any treatment relationship you have with healthcare providers at UW-Madison, UW Health or any affiliated organizations, or any services you receive from them. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights.

Your authorization for researchers to use your protected health information (PHI) will last until the research study is done. However:

- You can choose to take back your authorization for researchers to use your health information. You can do this at any time before or during your participation in the research.

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- If you take back your authorization, information that was already collected may still be used and shared with others, but the researchers will no longer be able to collect NEW information about you.
- If you take back your authorization, you will not be able to take part in the research study.
- To take back your authorization, you will need to tell the researchers by writing to the Lead Researcher, Justine Yang Bruce, MD, at WIMR Room 7105, 1111 Highland Avenue, Madison, WI 53705.

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

What are my other choices if I do not take part in this study?

You do not have to be in this research study to get care for your recurrent head and neck cancer. If you decide not take part in the study, you have other choices.
For example:

You may decide not to get treatment, but receive comfort care to help you stay as active and comfortable as possible.

You may choose to get the regular care described above for head and neck cancer.

Will being in this study help me in any way?

Being in this study may lessen the side effects of standard full dose EBRT treatments. The study treatment may work better than standard care for your condition, but we cannot promise this will happen. The study treatment might not work at all, or it might have bad side effects. Even if the study does not help you directly, your participation in this study may help other people in the future by helping us learn more about how CLR 131 and EBRT work together.

Will I receive the results of research tests?

The SPECT/CT imaging is being done specifically to determine the amount of the CLR 131 your tumor absorbs. We will not review these scans to look for other kinds of

information, and as a result, you will not be informed of any unexpected findings. The results of your images will be placed in your medical record. The results from your blood tests and the modified barium swallow will also be placed in your medical record.

The results from the saliva collection and oral profile tests as well as the QOL questionnaire results will not be reported.

What are the risks?

While on the study, you are at risk for side effects. You should discuss these with the study doctor and/or your regular doctor. There also may be other side effects that we cannot predict. Other drugs may be given to treat the side effects or make them less uncomfortable. Many side effects go away shortly after the treatment is stopped, but in some cases side effects can be serious or long-lasting or permanent. The side effects may range from mild to life threatening. There is a risk of death from this investigational treatment study.

<u>CLR 131</u>:

The study drug is investigational, and the risks or discomforts are not well known. Because we are testing different doses of CLR 131 to find the highest safe dose, there is a risk that the dose you receive is too low to have an effect on your tumor or that it is high enough to have severe side effects.

Since CLR 131 is a radioactive drug and the radiation takes time to clear out of your body after treatment, you could expose others (like family or caregivers) to radiation. Because of this, you may be asked to stay in a lead-shielded room at University of Wisconsin for up to a week after each infusion.

Side effects may include the following:
Very common (may affect more than 1 in 10 people):

- Fatigue (a feeling of being weak and tired or a lack of energy) (37%)
- Nausea (12%)
- Anemia (decreased number of red blood cells) which may cause you to feel tired or short of breath (55%)
- Decreased numbers of certain types of white blood cells (53%)
  - neutrophil decreased (50%)
  - lymphocytes (31%) which can increase the risk of infection

Decreased number of a type of blood cell that help to clot blood (platelet) which can cause bruising or increase the risk of bleeding (72%)
· Low levels of phosphorus in the blood which could cause muscle weakness or irritability (15%)

Not all of the adverse effects of CLR 131 are known, so it is important to report all adverse effects to the study team. For example, you could have an allergic reaction to the infusion of the study drug. This can range from a mild skin rash to a more severe reaction, such as facial swelling, throat tightness, increased heart rate, difficulty breathing, lowered blood pressure, and rarely death. This is usually temporary and may require additional medications.

EBRT of Head and Neck:

Common side effects include:

Painful sores in the mouth
difficulty swallowing which may necessitate a feeding tube
dry mouth
change in taste and smell
reduced saliva production
hoarseness
radiation skin damage
ear pain/infection
hearing loss
fatigue
weight loss
dehydration requiring IV fluids and electrolyte replacement
hair loss
tooth decay
decreased thyroid function which could cause fatigue, weakness, weight gain, hair loss

Rare and serious side effects include:

breathing and swallowing issues that require a tracheotomy (incision in windpipe to aid in breathing)
nerve damage in the head and neck region

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radiation necrosis (bone death) of the jaw
damage to the larynx (voice box) or nerves
damage to the skin, soft tissues or other parts of the head and neck that may require a surgery to correct
damage to the spinal cord which may cause permanent weakness

Thyroid Protection Medication:
To protect your thyroid from any possible exposure to radioactive iodine, thyroid protection medication such as potassium iodide is required to be taken by mouth at least 24 hours before your dose of CLR 131 and will continue for 14 days after the dose of CLR 131.

Side effects potassium iodide may include the following:

Nausea
Vomiting
Stomach ache
Diarrhea
Metallic taste in the mouth
Fever
Headache

Risks or discomforts of other study procedures:
The following risks are all temporary:

Blood samples: You may feel inconvenienced or discomforted by the needle sticks that are required for drawing blood. Bruising or infection could occur at the puncture site(s).

Saliva and oral swab collection: You may experience dry mouth.

Oral profile exam: You may feel slightly out of breath immediately following the measurement for a voluntary cough. You may experience discomfort or soreness of the tongue.

IV insertion: Most catheters are temporarily placed in the arm by way of a needle stick. Subjects may feel inconvenienced or discomforted by the needle stick. Bruising or infection may occur at the puncture site.

Vital signs: You may feel inconvenienced by the measurement of your vital signs.

You may feel inconvenienced by having to return for multiple appointments at the clinic for follow up visits.

You may feel inconvenienced by having to take thyroid protection medication for approximately 42 days.

You may feel inconvenienced if your treatment dose of CLR 131 requires you to be hospitalized for 2-7 days of observation.

Reproductive Risks:
The study procedures may harm a fetus or breastfeeding baby. If you are pregnant or breastfeeding, you cannot take part in this study. If you are able to become pregnant, you must have a pregnancy test before you begin the study. You should not get pregnant, breastfeed, or father a baby while in this study. All study participants must avoid becoming pregnant or causing a pregnancy while they are on study treatment/going through study procedures and for 6 months after your study participation ends.

Because study procedures during pregnancy may cause birth defects, safeguards are required to avoid becoming pregnant or causing a pregnancy. If you or your partner can get pregnant, it is important while on this study for you to either use birth control or not have sex that could result in pregnancy. Check with your study doctor about what kind of birth control methods to use and how long to use them. Appropriate forms of birth control could include oral contraceptives, condoms, diaphragms, intrauterine devices, Norplant, or Depo-Provera. Some birth control methods might not be approved for use in this study.

Women should not breastfeed while on this study. Check with your doctor about how long you should wait to breastfeed after you stop study treatment.

If you or your partner becomes pregnant while on this study the study sponsor will be informed. You (or your partner) will be reminded of the risks of the pregnancy and the study sponsor may ask that the pregnancy be monitored. If you (or your partner) were to become pregnant, it is not known what the risks to the embryo or fetus might be.

Other
We do not know what side effects could occur if the study drug is combined with other drugs or alcohol. Therefore, you should always discuss the use of alcohol or any drugs with your physician while you are taking part in this study. These drugs include ones you can buy on your own, ones you receive from your doctor, or illegal drugs. In addition, all medications and nutritional supplements (including vitamins, nutritional drinks and bars) you are currently taking should be reviewed with the study nurse and/or physician before starting this study. While on study, you should also consult with study staff before starting any new medications or nutritional supplements. While you are on this study, you should not receive any other treatment for your cancer (this includes any chemotherapy, radiation, surgery, or any other agents used to reduce or eliminate your tumors). If your doctor decides that one of these options would be better for you, you will be taken off of this study.

For more information about risks and side effects, ask the study doctor.

There is a risk that your information could become known to someone not involved in this study.

Will being in this study cost me anything?

There will be no cost to you for the investigational drug CLR 131, the thyroid protection medication that you take, the SPECT/CT imaging that is done to look at the CLR 131 uptake, or the saliva collection and analysis.

You or your insurance company will have to pay for all costs considered to be standard cancer care treatments and are needed as a result of receiving cancer care including co-payments and deductibles. Costs that will be charged to you or insurance include but are not limited to: administration of the CLR 131 therapy, hospitalization for observation after CLR 131 dosing if necessary, bloodwork drawn for safety purposes, modified barium swallow exams, physician visits and imaging scans used to monitor your cancer. You will have to pay for any costs your insurance does not cover. If you have any questions about these costs, or what out-of-pocket expenses you may have to pay, you should contact your insurance company. If you do not have health insurance, you will have to pay all costs for your medical care just as you would if you did not take part in this study.

If you need treatment for side effects while you are on the study, you or your insurance will need to pay for this treatment.

Will I be paid or receive anything for being in this study?

We will pay you $50 for the test dose imaging timepoint and $200 for completion of all 4 imaging timepoints after your therapeutic CLR 131 infusion.

Commercial product information

CLR 131 is not approved by the U.S. FDA and is available for research use only. The information obtained from this research may be of commercial value, but it is not expected that you will share in any potential profits from the commercialization of products developed from studying your participation in this study.

What happens if I am injured or get sick because of this study?

If you are injured or get sick because of this study, medical care is available to you through UW Health, your local provider, or emergency services, as it is to all sick or injured people.

If it is an emergency, call 911 right away or go to the emergency room.
For non-emergency medical problems, contact the study team for instructions.
Call the Lead Researcher, Justine Yang Bruce, MD, at 608-263-8500 to report your sickness or injury. For UW Cancer Center Johnson Creek call Newton Hurst, M.D., at 920-699-3500.

Here are some things you need to know if you get sick or are injured because of this research:

If the sickness or injury requires medical care, the costs for the care will be billed to you or your insurance, just like any other medical costs.
Your health insurance company may or may not pay for this care.
No other compensation (such as lost wages or damages) is usually available.
UW-Madison and UW Health do not have a program to pay you if you get sick or are injured because of this study.
By signing this consent form and taking part in this study, you are not giving up any legal rights you may have. You keep your legal rights to seek payment for care required because of a sickness or injury resulting from this study.

How will the researchers keep my research information confidential?

We have strict rules to protect your personal information and protected health information (PHI). We will limit who has access to your health information, your name, address, phone number, and other information that can identify you. We will also store this information securelyThe study is protected by a Certificate of Confidentiality from the Food and Drug Administration (FDA). This means that even if the police or courts ask to look at the data we have collected, we will not share any information that would identify you as a participant in the study.
. Once issued, the Certificate will retroactively cover information collected since the beginning of the study. We may publish and present what we learn from this study, but none of this information will identify you directly without your permission.

However, we cannot promise complete confidentiality. Federal or state laws may permit or require us to show information to university, government officials or Cellectar Biosciences responsible for monitoring this study. This includes access to your medical records so that study monitors, auditors, the Institutional Review Board and regulatory authorities can verify study procedures and/or data. These groups will maintain your confidentiality. By signing this consent form, you are authorizing this access to your records. We may also have to tell appropriate authorities, such as child protective services or health care providers, if we learn during the study that you or others are at risk of harm (for example, due to child or elder abuse, or suicidal thoughts).

Authorizing the research team to use your PHI means that we can release it to the people or groups listed below for the purposes described in this form. Once your health information is released outside UW-Madison or UW Health it may not be protected by privacy laws and might be shared with others. Also, with appropriate institutional permissions and confidentiality protections, we might use information that we collect during this study for other research or share with other researchers without additional consent or authorization from you or your legally authorized representative.

Who at UW-Madison can use my information?

Members of the research team
Offices and committees responsible for the oversight of research
Personnel who schedule or perform medical tests or procedures, handle accounting and billing, or do other tasks related to this study

Who outside the UW-Madison may receive my information?

U.S. Office for Human Research Protections
The U.S. Food and Drug Administration (FDA)
Cellectar

Will information from this study go in my medical record?

Some of the information that we collect about you for this study will be put in your medical record. This includes information about the procedures performed in the hospital. All of the information regarding your cancer treatment will be in your medical record. Both you and your UW Health providers will be able to see these results. Information from the Quality of life surveys will not be put into your medical record as that was collected for research purposes only.

What if I have questions?

If you have questions about this research, please contact the Lead Researcher, Justine Yang Bruce, MD at 608-263-8500. For UW Cancer Center Johnson Creek contact Newton Hurst, M.D., at 920-699-3500. If you have any questions about your rights as a research subject or have complaints about the research study or study team, contact UW Health Patient Relations at 608-263-8009. The Patient Relations Representatives work with research subjects to address concerns about research participation and assist in resolving problems.

We are requesting your email address so we can exchange information about scheduling and questionnaires. Email is generally not a secure way to communicate about your health as there are many ways for unauthorized users to access email. You should avoid sending sensitive, detailed personal information by email. Email should also not be used to convey information of an urgent nature. If you need to talk to someone immediately, please contact the Lead Researcher, Justine Yang Bruce, MD at 608-263-8500. You do not have to provide your email address to participate in this study.

_____Yes, you may use email to contact me for this study.

_____No, I do not want to be contacted by email.

Agreement to participate in the research study

You do not have to sign this form. If you refuse to sign, however, you cannot take part in this research study.

If you sign the line below, it means that:

- You have read this consent and authorization form.
- You have had a chance to ask questions about the research study, and the researchers have answered your questions.
- You want to be in this study.
- You give authorization for your protected health information to be used and shared as described in this form.

Printed Name of Research Participant

Signature of Research Participant Date

Signature of Person Obtaining Consent and Authorization Date

****You will receive a signed and dated copy of this form****