

Study Guide

Support for you at every step

Thank you for taking part in this study

We really appreciate **your time, trust and commitment**. Your participation will help to develop new future treatments for people like you, living with biliary tract cancer.

Now that you're starting your study treatment, this guide contains all the information you may need to help you throughout your time on this study.

The first half contains some information to remind you why we are doing this study, and what you can expect as you take part.

This includes:

- ✓ What treatment you will receive
- ✓ How often you will receive your treatment
- ✓ What happens after your treatment finishes
- ✓ How you can take care of yourself during the study

The second half contains a guide to your study visits, which you can use to help prepare, and know what to expect each time you visit the study clinic.

You will be able to:

- ✓ Write down the date and time of your next visit
- ✓ Check which tests and assessments you may have
- ✓ Tear out each visit page to take with you to the study clinic
- ✓ Space to write down any questions or concerns you may want to discuss with your study doctor at your next visit

We have also included a separate guide for your caregiver, to help them understand what you will be doing, and how they can best support you during this study.





Remember, taking part in this study is completely your choice. You can choose to stop taking part at any time, and it will not affect the care you receive in any way. If you would like to stop taking part, please speak to your study doctor so they can discuss the next steps with you.

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Why are we doing this study?

ARTEMIDE-Biliary02 is looking at whether combining a new drug called **rilvegostomig** with **chemotherapy** is safe and effective for people with advanced biliary tract cancer who have **not yet received treatment**.



Rilvegostomig
(immunotherapy)



Cisplatin/gemcitabine
(chemotherapy)

Rilvegostomig is a new type of drug called an **immunotherapy** and it works by helping your immune system to find and attack cancer cells.

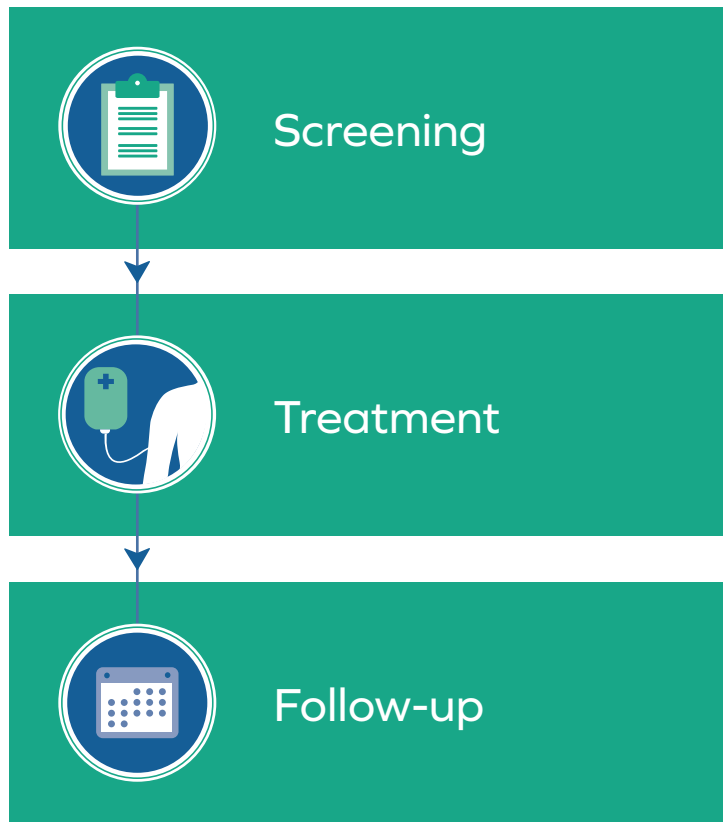


You can find out more about
how rilvegostomig works in your
Informed Consent Form (ICF).



What can I expect as I take part?

This study is split into 3 parts:



You are here

Understanding your treatment

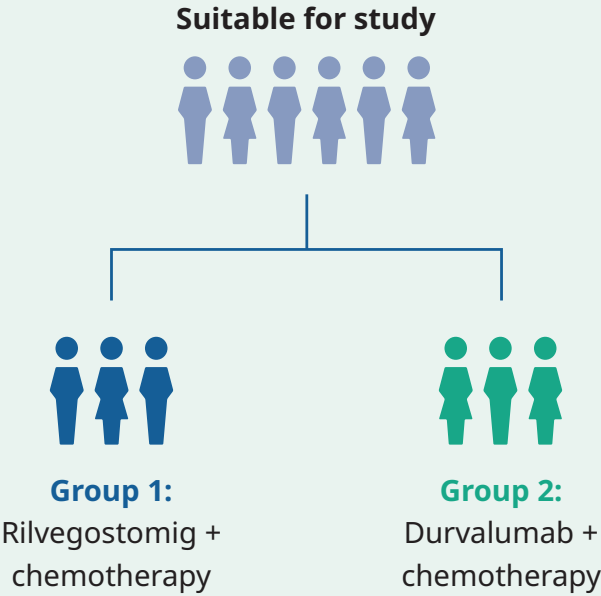
To find out more about **rilvegostomig** and how it works, we need to compare it to the current **standard-of-care** treatment for biliary tract cancer, which is a combination of another type of immunotherapy called **durvalumab**, and **chemotherapy**.

Standard-of-care means that it is currently the approved treatment used for biliary tract cancer.

Which treatment will I receive?

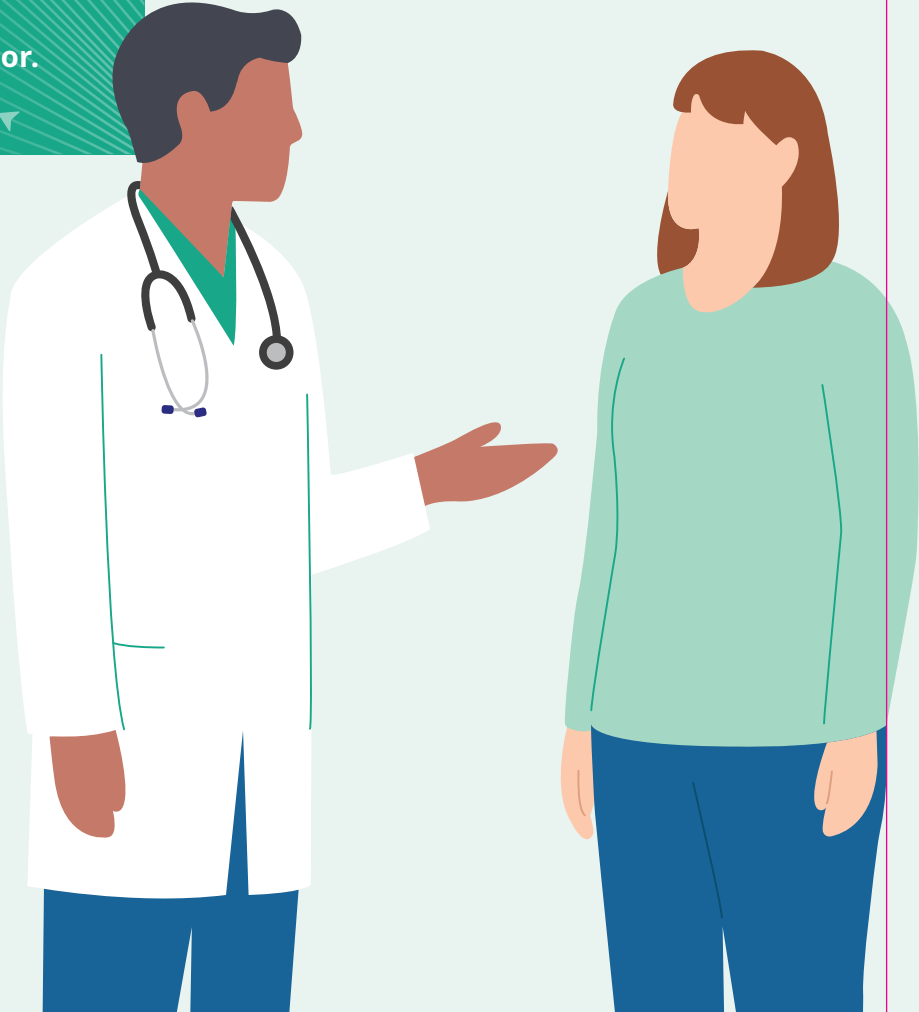
Everyone who joins this study will be **randomly split** into **1 of 2 treatment groups**. This means that you will have a **50% chance** of receiving **rilvegostomig** or **durvalumab**.

However, you are guaranteed to receive the standard-of-care chemotherapy for this study. The standard-of-care chemotherapy is two treatments, called gemcitabine and cisplatin.



During this study, both you and your study doctor will know which treatment you are receiving. Your study doctor will discuss this with you during your first treatment visit.

If you have any questions or concerns while you are receiving your treatment, please do not hesitate to speak with your study doctor.



How often will I receive my treatment?

Treatment in clinical studies is often measured in **cycles**. In one cycle, you will receive your treatment, followed by some time to **rest and recover** before your next dose.

The first 8 treatment cycles in this study are each 3 weeks long. During each of these 3-week cycles, you will receive **rilvegostomig** or **durvalumab** on **Day 1**, and gemcitabine and cisplatin on **Day 1** and **Day 8**.

Then from Cycle 9 onwards, you will continue receiving either **rilvegostomig once every 3 weeks** or **durvalumab once every 4 weeks**.

If receiving rilvegostomig:

	Cycle 1-8			Cycle 9 onwards		
	Week 1	Week 2	Week 3	Week 1	Week 2	Week 3
Rilvegostomig	✓			✓		
Chemotherapy	✓	✓				

If receiving durvalumab:

	Cycle 1-8			Cycle 9 onwards			
	Week 1	Week 2	Week 3	Week 1	Week 2	Week 3	Week 4
Durvalumab	✓			✓			
Chemotherapy	✓	✓					



How will I receive the study treatment?

Each treatment in this study will be given to you through a drip in your arm, called an **intravenous (IV) infusion**. This is sometimes called an **IV**, or just an **infusion**.

All of your treatments will be given to you in line with the guidelines in your country.



These infusions may take a while to complete. You will also need to have some tests and assessments at each visit. Your study doctor will let you know how long each visit, and each infusion, is likely to take.

What happens after the treatment period?

After you finish your study treatment, you'll be asked to come back for some **follow-up** visits.

You will have a visit **30 days** and **90 days** after your last dose of study treatment to have some tests and assessments.

Then, you will only need to visit the study clinic **once every 12 weeks** for a few scans of your tumor. You may not need a scan, in which case your visit may just be a phone call with the study doctor to see how you are.



These visits are an important part of the study so that the study team can continue to monitor your health and well-being over a longer period of time.

You can find more information about your visits and what to expect in the **Visit pages** towards the back of this guide.

What will I need to do at home?

Throughout the study, you'll be asked to complete some **short questionnaires** on a **mobile device**.

During your first treatment visit, the study team will provide you with a mobile device, or they will help you to download an App onto your personal device if you would prefer. The study team will give you detailed training on how to use the App to complete your questionnaires.

These questions are about how you are feeling, and any side effects you may be experiencing. They should take no longer than **2-10 minutes** to complete each day.

Your voice matters, and we really need to hear about **your** experiences. If you're able to, please complete the questionnaires **by yourself, without any help or input from others**. There are no right or wrong answers, or penalties if you answer any incorrectly.



These questionnaires are really important, as they will help the study team to understand how you may be responding to the study treatment. Your answers will help the study team give you any additional support that you may need.

How can I take care of myself during the study?



Side effects

As with all medicines, there may be some side effects caused by the study treatments. Your study doctor and the study team will be closely monitoring your health throughout the study, so any side effects can be identified quickly.

If you do notice any changes in your health please let the study team know so they can provide the help and support that you may need as soon as possible. Even if it seems small, some effects may become harder to treat if not managed quickly. For more information on possible side effects, please have a look in your Informed Consent Form.

Remember, your safety and well-being are the study team's number one priority. They will be there to provide you with any care and support that you may need.



Exercise

If you are able to, staying active is a really good way to improve how you may be feeling. It can reduce stress, improve sleep, give you more energy and support your immune system.

But it's important that you carefully plan your exercise, depending on how you are feeling. Doing too much could also make you feel worse.

If you would like to add some daily exercise to your routine, please speak with a member of your study team for some advice.



You may find some comfort in speaking with the study team, who will be there to listen and provide support.

- Do you have any questions about your diagnosis?
- Is there anything else the study team could do to support you?
- Do you have any questions about the tests and assessments?
- Do you need more advice on how to manage any side effects?
- What makes you feel motivated to take part in this study?

These visit pages hope to make your participation in this study as easy as possible.

They cover:

- ✓ The date and time of your next visit
- ✓ What you can expect during the visit
- ✓ How you can prepare
- ✓ Any other important information you need to know



Each page also has a notes section for you or your study doctor to write down any comments, questions or feedback you may feel is necessary at each visit.

What can I expect when I visit the study clinic?

When you visit the study clinic, you will:

- ✓ Meet with your study team
- ✓ Receive your study treatment
- ✓ Have some tests and assessments as part of your routine care and as part of the study
- ✓ Receive any help or support you may need



What tests and assessments might I have?

At each visit, you will have some tests and assessments so the study team can monitor your health and well-being, and so we can find out more about the study treatment.

These might include:



Conversations with your study doctor about how you are feeling



Routine tests, like physical examinations, height and weight measurements, or blood pressure and blood oxygen measurements



Blood tests



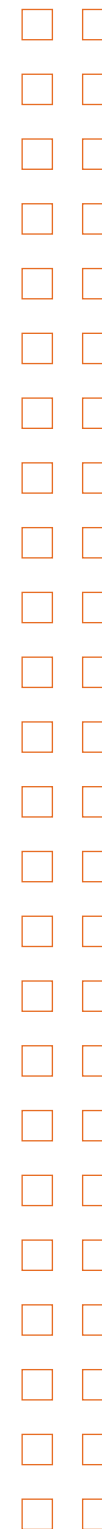
Scans of your body, which might include:

- Computed tomography (CT) scans, or magnetic resonance imaging (MRI) scans



Pregnancy tests

- Only if you're able to have children
- These may be a blood or urine test



If there are signs that you may be having certain symptoms or side effects, your study doctor may request that you have:



Heart tests, which might include:

- Electrocardiograms (ECGs), echocardiograms (ECHOs) or multigated acquisition (MUGA) scans



Urine tests

We appreciate that some of your visits might feel quite long. You can bring things from home, like a book or your phone, to pass the time. Please bring a friend or loved one with you too, if you like. A member of the study team will also be available for any help or support.

How can I prepare for visits?

Preparing for visits will be different for everyone.
But we would recommend:



Wearing comfortable, loose clothing



Being well rested



Making sure you've eaten and are hydrated



Checking which tests and assessments you will have before your visits

What should I do if I cannot attend a study visit?

It is really important that you come for all of your study visits if you're able, but we want to make this as easy as possible. If you cannot attend a visit, please speak to your study team so that they can rearrange a more suitable date and time.

Is there any help and support available for my visits?

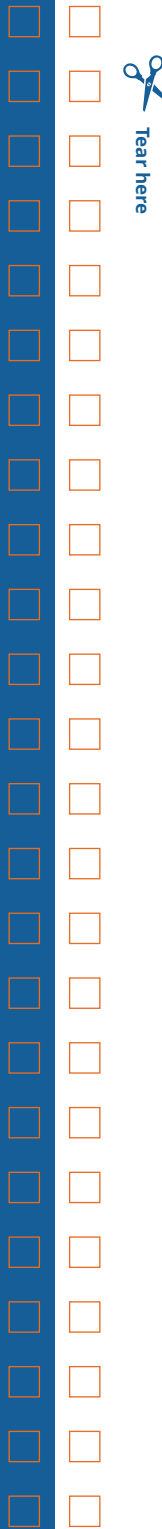
Depending on the local rules in your area, you may be able to claim back costs during your visits, for example, parking or travel costs. Your study team will be able to discuss this possibility with you in detail.

Visit pages

This section of the guide will help you understand what to expect at each visit.

You can use the space in each box to record the date, time and length of your next visit.

If you like, you can also cut or tear out the visit pages and bring them with you to your visits.



Cycle 1 Day 1

Date:

Time:

Visit length:

What tests and assessments will I have?



Conversations with your doctor



Routine tests, like physical examinations, blood pressure, heart rate and weight



Blood tests, which help to monitor your health, well-being and how well the study treatment may be working

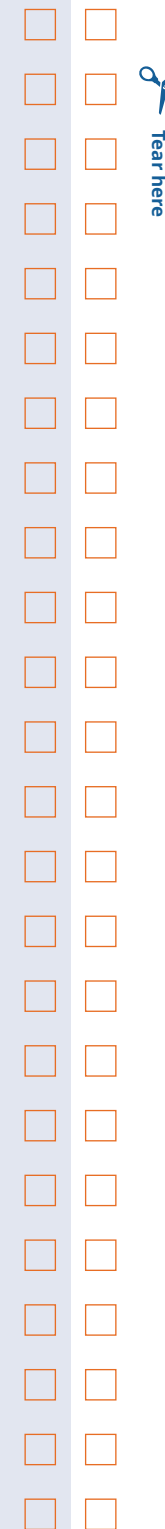


Pregnancy test (if applicable)

Important information about this visit

- During this visit, you will receive your **first dose of study treatment**
- If you agreed to take part in the **optional DNA (genomics) research**, the study team may take an extra blood sample
- The study team will provide you with a study phone (or will download an app onto your personal mobile device) to answer your questionnaires, and they will train you how to use it

Notes

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Cycle 1 Day 8

Date:

Time:

Visit length:

What tests and assessments will I have?



Conversations with your doctor



Routine tests, like physical examinations, blood pressure, heart rate and weight

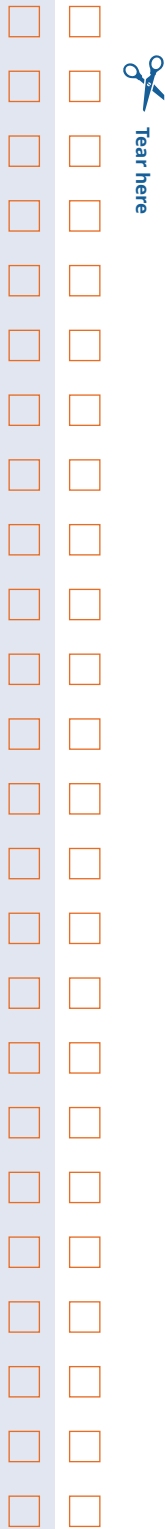


Blood tests, which help to monitor your health, well-being and how well the study treatment may be working

Important information about this visit

- At this visit, you'll receive your next dose of **chemotherapy**

Notes



Cycle 2 Day 1

Date:

Time:

Visit length:

What tests and assessments will I have?



Conversations with your doctor



Routine tests, like physical examinations, blood pressure, heart rate and weight



Blood tests, which help to monitor your health, well-being and how well the study treatment may be working

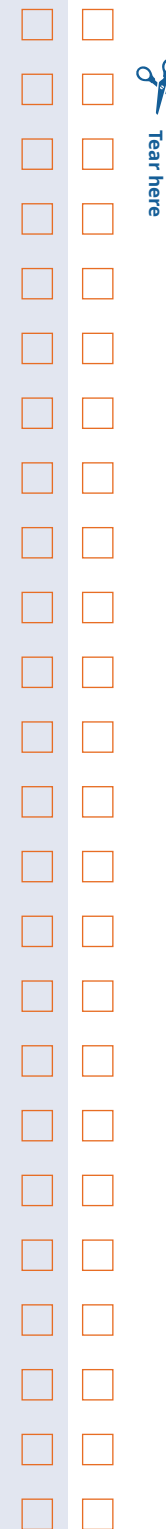


Pregnancy test (if applicable)

Important information about this visit

- At this visit, you'll receive your next dose of **study treatment**

Notes

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Cycle 2 Day 8

Date:

Time:

Visit length:

What tests and assessments will I have?



Conversations with your doctor



Routine tests, like physical examinations, blood pressure, heart rate and weight

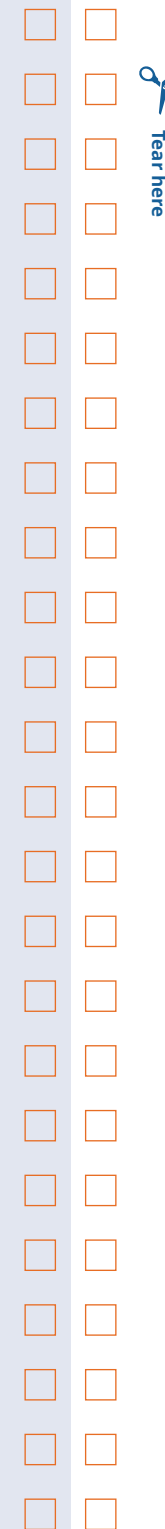


Blood tests, which help to monitor your health, well-being and how well the study treatment may be working

Important information about this visit

- At this visit, you'll receive your next dose of **chemotherapy**

Notes

[illegible]

Cycle 3 Day 1

Date:

Time:

Visit length:

What tests and assessments will I have?



Conversations with your doctor



Routine tests, like physical examinations, blood pressure, heart rate and weight



Blood tests, which help to monitor your health, well-being and how well the study treatment may be working



Pregnancy test (if applicable)

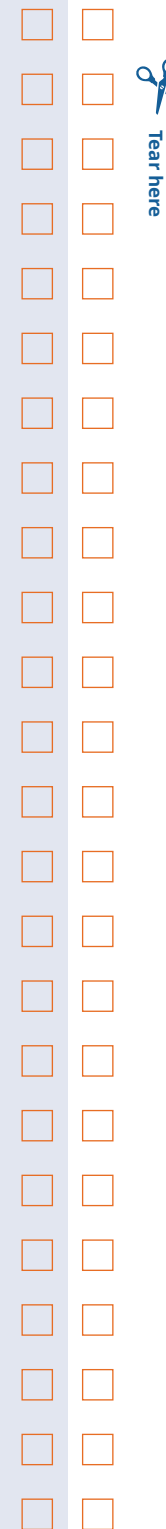


Scans of your body

Important information about this visit

- At this visit, you'll receive your next dose of **study treatment**

Notes

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Cycle 3 Day 8

Date:

Time:

Visit length:

What tests and assessments will I have?



Conversations with your doctor



Routine tests, like physical examinations, blood pressure, heart rate and weight

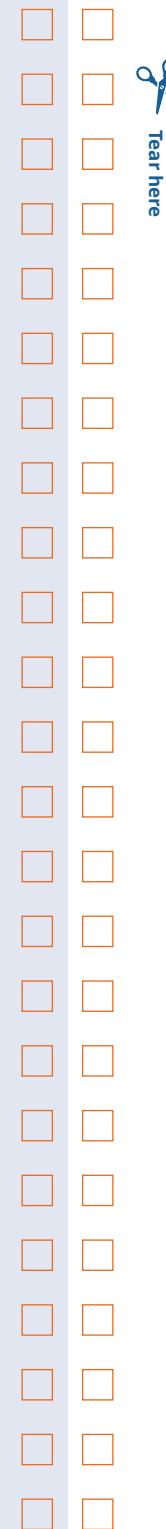


Blood tests, which help to monitor your health, well-being and how well the study treatment may be working

Important information about this visit

- At this visit, you'll receive your next dose of **chemotherapy**

Notes

[illegible]

Cycle 4 Day 1

Date:

Time:

Visit length:

What tests and assessments will I have?



Conversations with your doctor



Routine tests, like physical examinations, blood pressure, heart rate and weight



Blood tests, which help to monitor your health, well-being and how well the study treatment may be working

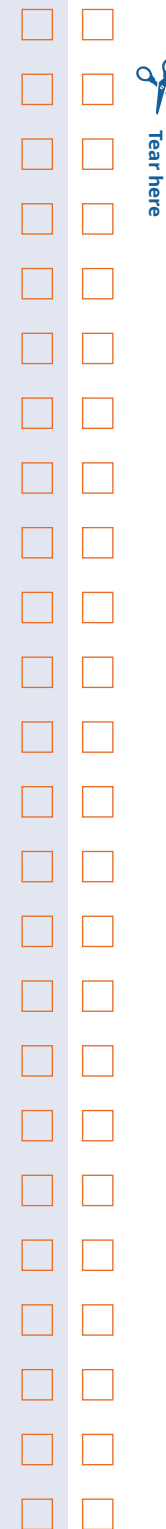


Pregnancy test (if applicable)

Important information about this visit

- At this visit, you'll receive your next dose of **study treatment**

Notes

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Cycle 4 Day 8

Date:

Time:

Visit length:

What tests and assessments will I have?



Conversations with your doctor



Routine tests, like physical examinations, blood pressure, heart rate and weight

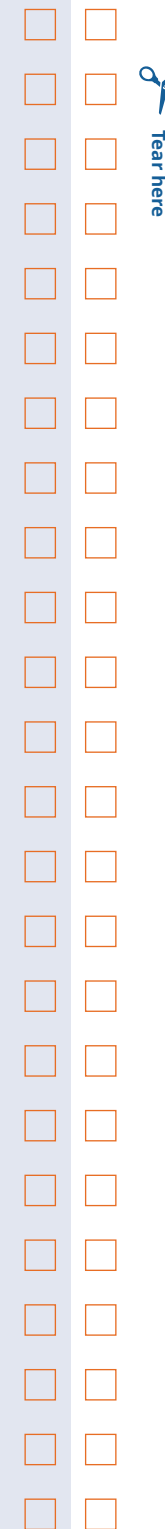


Blood tests, which help to monitor your health, well-being and how well the study treatment may be working

Important information about this visit

- At this visit, you'll receive your next dose of **chemotherapy**

Notes

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Cycle 5 Day 1

Date:

Time:

Visit length:

What tests and assessments will I have?



Conversations with your doctor



Routine tests, like physical examinations, blood pressure, heart rate and weight



Blood tests, which help to monitor your health, well-being and how well the study treatment may be working



Pregnancy test (if applicable)

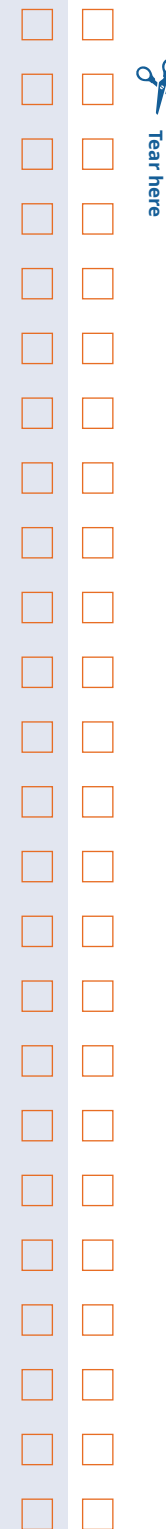


Scans of your body

Important information about this visit

- At this visit, you'll receive your next dose of **study treatment**

Notes

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Cycle 5 Day 8

Date:

Time:

Visit length:

What tests and assessments will I have?



Conversations with your doctor



Routine tests, like physical examinations, blood pressure, heart rate and weight

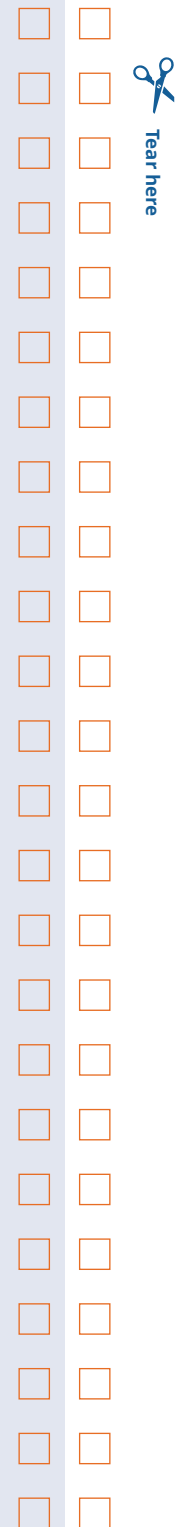


Blood tests, which help to monitor your health, well-being and how well the study treatment may be working

Important information about this visit

- At this visit, you'll receive your next dose of **chemotherapy**

Notes



Cycle 6 Day 1

Date:

Time:

Visit length:

What tests and assessments will I have?

Conversations with your doctor

Routine tests, like physical examinations, blood pressure, heart rate and weight

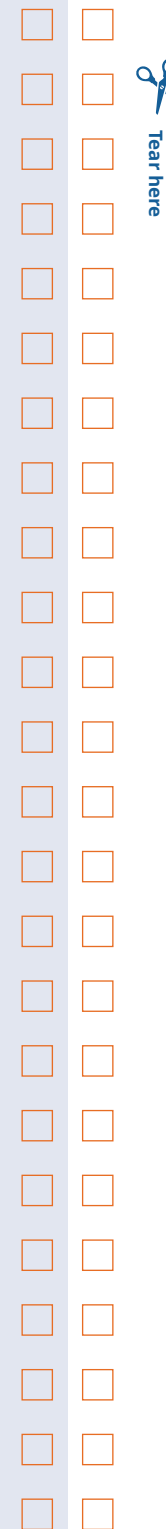
Blood tests, which help to monitor your health, well-being and how well the study treatment may be working

Pregnancy test (if applicable)

Important information about this visit

- At this visit, you'll receive your next dose of **study treatment**

Notes

[illegible]

Cycle 6 Day 8

Date:

Time:

Visit length:

What tests and assessments will I have?



Conversations with your doctor



Routine tests, like physical examinations, blood pressure, heart rate and weight

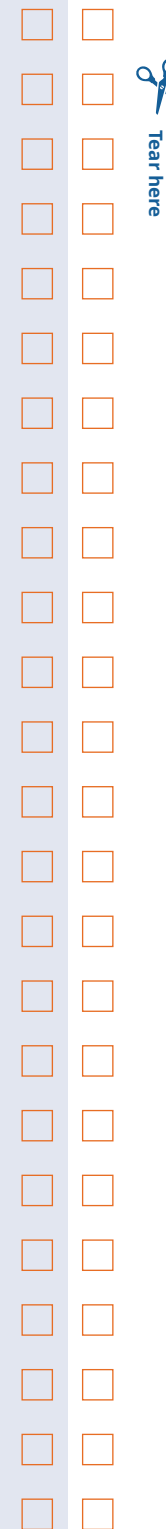


Blood tests, which help to monitor your health, well-being and how well the study treatment may be working

Important information about this visit

- At this visit, you'll receive your next dose of **chemotherapy**

Notes

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Cycle 7 Day 1

Date:

Time:

Visit length:

What tests and assessments will I have?



Conversations with your doctor



Routine tests, like physical examinations, blood pressure, heart rate and weight



Blood tests, which help to monitor your health, well-being and how well the study treatment may be working

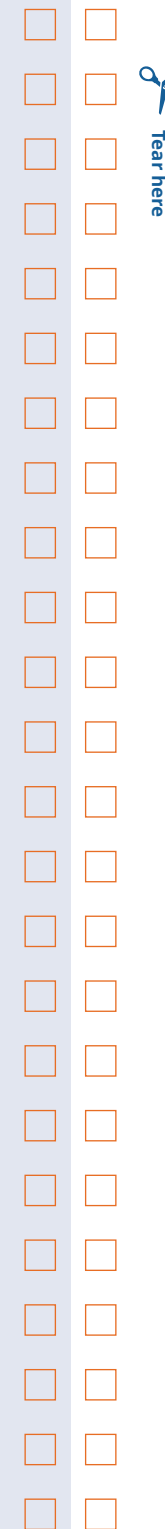


Pregnancy test (if applicable)

Important information about this visit

- At this visit, you'll receive your next dose of **study treatment**

Notes

[illegible]

Cycle 7 Day 8

Date:

Time:

Visit length:

What tests and assessments will I have?



Conversations with your doctor



Routine tests, like physical examinations, blood pressure, heart rate and weight

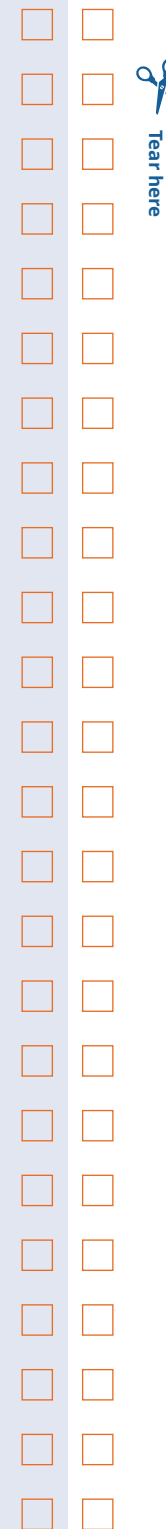


Blood tests, which help to monitor your health, well-being and how well the study treatment may be working

Important information about this visit

- At this visit, you'll receive your next dose of **chemotherapy**

Notes

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Cycle 8 Day 1

Date:

Time:

Visit length:

What tests and assessments will I have?



Conversations with your doctor



Routine tests, like physical examinations, blood pressure, heart rate and weight



Blood tests, which help to monitor your health, well-being and how well the study treatment may be working

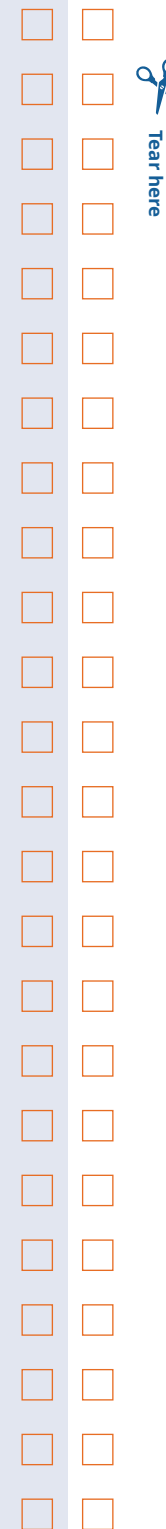


Pregnancy test (if applicable)

Important information about this visit

- At this visit, you'll receive your next dose of **study treatment**

Notes

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Cycle 8 Day 8

Date:

Time:

Visit length:

What tests and assessments will I have?



Conversations with your doctor



Routine tests, like physical examinations, blood pressure, heart rate and weight



Blood tests, which help to monitor your health, well-being and how well the study treatment may be working

Important information about this visit

- At this visit, you'll receive your final dose of **chemotherapy**

Notes

Cycle 9 onwards

From **Cycle 9 onwards**, you will keep receiving either **rilvegostomig** or **durvalumab**, but without chemotherapy. Your visits will now be:



Every 3 weeks if you're receiving **rilvegostomig**



Every 4 weeks if you're receiving **durvalumab**



Even though you will be seeing your study doctor less often than before, you can still contact them at any time if you have any questions or concerns.

If you stop receiving study treatment early for any reason, you will then move into the follow-up period of the study.

During these visits, you will have the same tests and assessments as you have already been having during the first 8 cycles.

These will include:



Conversations with your study doctor about how you are feeling



Routine tests, like physical examinations, blood pressure and heart rate



Blood and urine tests, which help to monitor your health and well-being



Pregnancy tests (if applicable)

You will also need to continue answering the weekly questionnaires on your mobile device.



Please use the spaces on the following pages to record any details of your study visits.

Cycle 9 onwards

Date:

Time:

Notes:

Date:

Time:

Notes:

Date:

Time:

Notes:

Date:

Time:

Notes:

Date:

Time:

Notes:

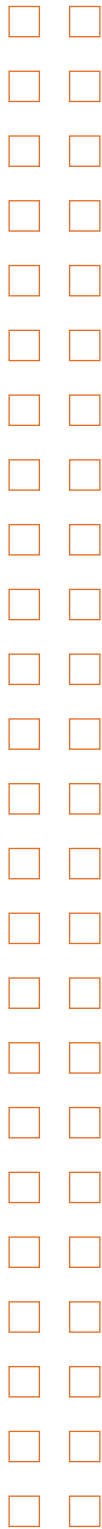
Date:

Time:

Notes:

Cycle 9 onwards

Date: _____ Time: _____ Notes: _____ _____ _____ _____ _____	Date: _____ Time: _____ Notes: _____ _____ _____ _____ _____	Date: _____ Time: _____ Notes: _____ _____ _____ _____ _____
Date: _____ Time: _____ Notes: _____ _____ _____ _____ _____	Date: _____ Time: _____ Notes: _____ _____ _____ _____ _____	Date: _____ Time: _____ Notes: _____ _____ _____ _____ _____



Cycle 9 onwards

Date: _____ Time: _____ Notes: _____ _____ _____ _____ _____	Date: _____ Time: _____ Notes: _____ _____ _____ _____ _____	Date: _____ Time: _____ Notes: _____ _____ _____ _____ _____
Date: _____ Time: _____ Notes: _____ _____ _____ _____ _____	Date: _____ Time: _____ Notes: _____ _____ _____ _____ _____	Date: _____ Time: _____ Notes: _____ _____ _____ _____ _____

Follow-up

Now that you have finished your study treatment, you will start the **follow-up period**.

Follow-up is split into 2 parts:



Safety follow-up visits, around 30 days (4 weeks) and 90 days (13 weeks) after your final dose of study treatment



Long-term follow-up, every 12 weeks after your last dose of study treatment

Tear here

Safety visit 1 (30 days after you last received treatment)

Date:

Time:

Visit length:

What tests and assessments will I have?



Conversations with your doctor



Routine tests, like physical examinations, blood pressure, heart rate and weight

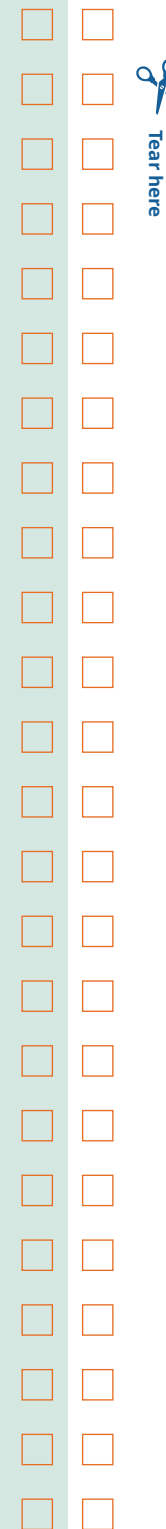


Blood tests, which help to monitor your health, well-being and how well the study treatment may be working



Pregnancy test (if applicable)

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Date: _____ Time: _____

Time:

What tests and assessments will I have?

- Conversations with your doctor
- Routine tests, like physical examinations, blood pressure, heart rate and weight
- Blood tests, which help to monitor your health, well-being and how well the study treatment may be working
- Pregnancy test (if applicable)



 Routine tests, like physical examinations, blood pressure, heart rate and weight



 Blood tests, which help to monitor your health, well-being and how well the study treatment may be working



 Pregnancy test (if applicable)



Study code: D702NC00001 Version no.: 1.0 Date: 10/07/2025 enUS

Notes

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Long-term follow-up

After safety follow-up visit 2, you will move into long-term follow-up. Here, the study doctors will continue to collect information about how well the study treatment has worked over a longer period of time.

Your study visits will be **every 12 weeks**, where you keep having some tumor imaging scans. If you're not due to have a scan, your visits will usually just involve quick check-ups to find out how you are.

If you begin a new treatment for your cancer, the study may still regularly contact you by telephone to check how you are.



Further support

We understand that this may be a difficult time for you and your close ones. But we really appreciate your commitment to this study.

If you need any further support during the study, please contact the study doctor or a member of the study team.

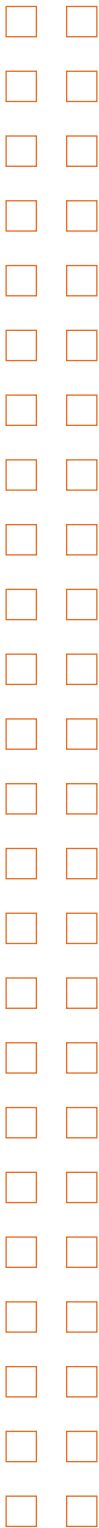
Study doctor

Name:

Address:

Contact number:

Email:



Study coordinator, for example, a study nurse

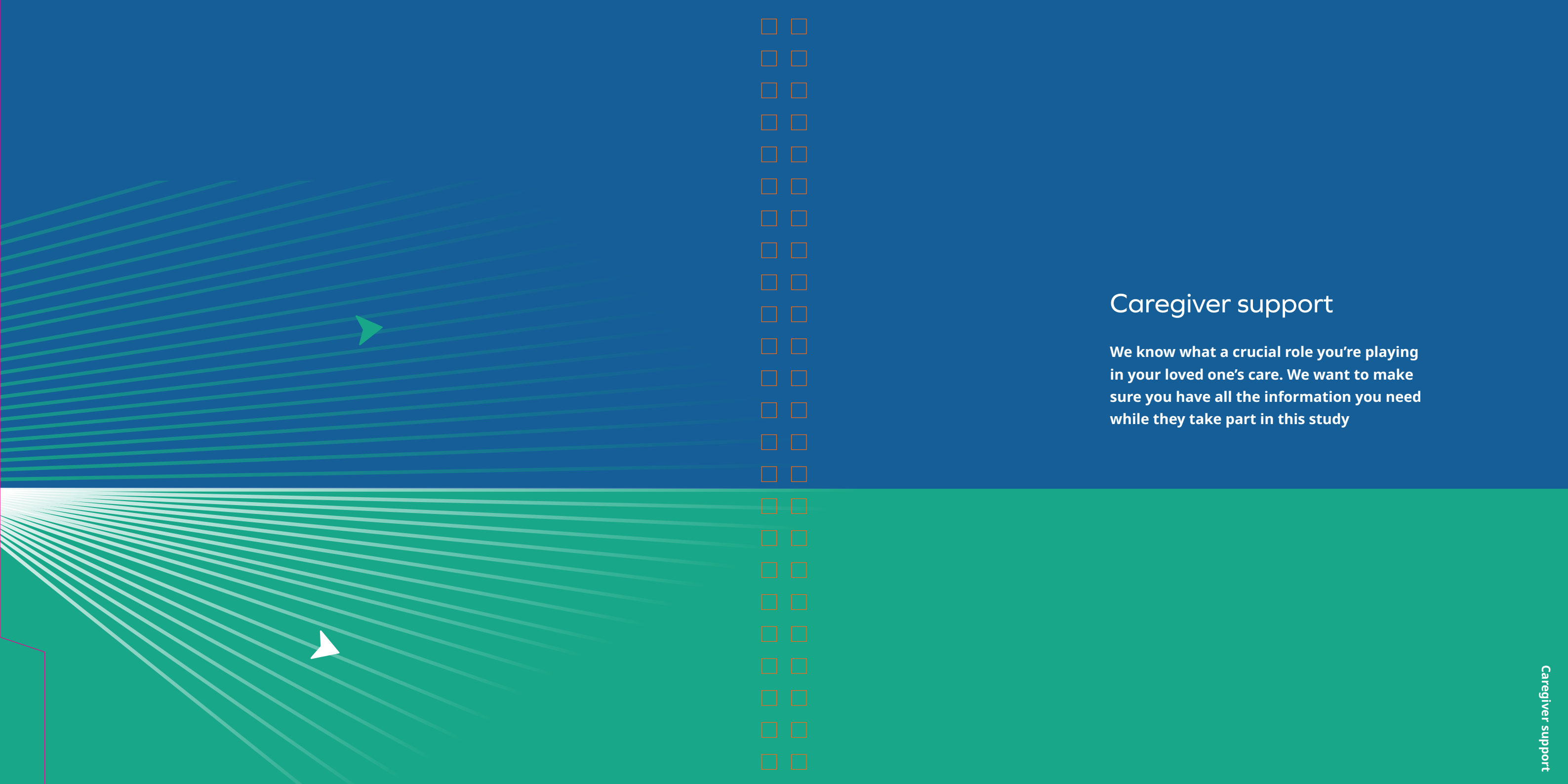
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Address:

Contact number:

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Caregiver support

We know what a crucial role you’re playing in your loved one’s care. We want to make sure you have all the information you need while they take part in this study

What is this study about?

ARTEMIDE-Biliary02 is a clinical study looking at combining a new drug called rilvegostomig with chemotherapy for people with biliary tract cancer.

We are looking at how it compares with the current standard-of-care treatment, of durvalumab with chemotherapy.

What are the study treatments and how do they work?

Rilvegostomig is a type of immunotherapy, which works by helping the immune system to find and attack cancer cells. Durvalumab also works in a similar way.

Gemcitabine and cisplatin are both types of chemotherapy. They work by finding and attacking cells that grow quickly, for example, cancer cells.

By taking part, they will have a 50% chance of receiving either rilvegostomig or durvalumab, but are guaranteed to receive chemotherapy.

How will they receive their study treatment?

All treatments will be given through a drip into their arm, also called an IV infusion. These may take a while to complete, so feel free to join them for the whole time they are receiving their treatment.



What will your loved one be doing while taking part in the treatment part of the study?

Their treatment will be measured in cycles. One cycle is the time between one dose of study treatment and the next.

They will need to visit the study clinic on Day 1 and Day 8 of a 3-week cycle, for 8 cycles.

From Cycle 9 onwards, they will only need to visit the study clinic on Day 1 of each cycle. This will be every 3 weeks if they are receiving rilvegostomig, or every 4 weeks for durvalumab.

They will continue receiving treatment until their cancer gets worse, or if they need to stop for any other reason.

Once they have finished treatment, the study doctor will discuss their next treatment options with them.

If receiving rilvegostomig:

	Cycle 1–8			Cycle 9 onwards		
	Week 1	Week 2	Week 3	Week 1	Week 2	Week 3
Rilvegostomig	✓			✓		
Chemotherapy	✓	✓				

If receiving durvalumab:

	Cycle 1–8			Cycle 9 onwards			
	Week 1	Week 2	Week 3	Week 1	Week 2	Week 3	Week 4
Durvalumab	✓			✓			
Chemotherapy	✓	✓					

What will happen at each visit?

At each visit, they will receive their study treatment and have some tests and assessments to monitor their health and well-being. These tests may include blood tests, urine tests, scans of their tumor and routine tests such as blood pressure monitoring, physical examinations, and height and weight measurements.

What happens after the treatment period has ended?

After treatment, they will be asked to come back for some follow-up visits, where they will have a few more tests and assessments.

They will have a visit 30 days and 90 days after their last dose of study treatment, then they will have one visit every 12 weeks.

These follow-up visits are important, as they will allow the study team to monitor their health and well-being over a longer period of time, and provide any extra care and support they may need.

How will they be kept safe during the study?

Before they are allowed to start, clinical studies like this are reviewed and approved by a group of specialists to help protect the safety of everyone involved.

Throughout their time on the study, your loved one or friend will be receiving frequent and detailed health monitoring by a team focused on managing their condition.

If they experience any side effects or have any concerns while taking part, they will be quickly and efficiently managed under professional care.

If you or the person taking part in this study notices any changes in their health, no matter how big or small, you should contact the study team right away, and they will be able to provide the necessary help and support.

How can you help?

We know that you will want to provide the best care that you can, so here are a few things that may help you support your loved one during this study:

- ✓ Coming to their study visits with them to keep them company during their IV infusions
- ✓ Keeping detailed notes during their study visits
- ✓ Making sure your loved one follows their study doctor's advice
- ✓ Helping your loved one prepare for visits, for example, making sure they have eaten and are hydrated before each visit
- ✓ Watching out for any health changes and reporting them as soon as possible

[illegible]

Is there anything else you should know?

Regular care

While your loved one or friend takes part in this study, it will have no impact on their regular care whatsoever. If they stop taking part for any reason, their care will be returned to their regular doctor, who will be able to advise them on their next steps.

Free of charge

Taking part is completely free of charge. All treatment, tests and assessments, and support will be funded by the sponsor.

You may be able to claim back expenses related to the study, for example, parking or transport costs. Please speak to the study doctor to see if this is possible for your friend or loved one.

Looking after yourself

We know that, as a caregiver, this may also be a difficult time for you.
And we really appreciate the care you give for your loved one or friend.

While you are caring for someone else, it is really important that you look after yourself too.

If things become too much, it is important that you:

- ✓ Get more support when you need it, from patient groups or your own doctor
- ✓ Take some time to rest and do the things you enjoy
- ✓ Check in about visit support and reimbursement options
- ✓ Reach out to the study team for support or advice at any time
- ✓ Check if the study team could provide details of online forums
- ✓ Do ask others around you for help and support too

[illegible]

Thank you

Thank you for looking after your loved one while they take part in the study. If you have any questions or concerns, you can speak to the study doctor at any time.

Study Doctor

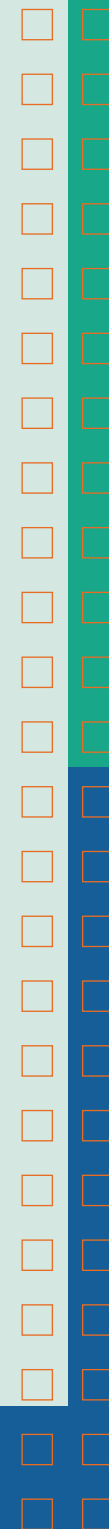
Name:

Contact number:

Email address:

Study address:

Notes

[illegible]

Thank you for considering ARTEMIDE-Biliary02

Your participation is vital as we try to
find new treatments for people like
you living with biliary tract cancer



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Version no.: 1.0
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enUS