Inotuzumab ozogamicin

Inotuzumab ozogamicin is a targeted medicine used to treat some people with acute lymphoblastic leukaemia (ALL).

Summary

- Inotuzumab ozogamicin is a type of targeted cancer drug. It is used to treat B-cell acute lymphoblastic leukaemia (ALL).
- It is approved for relapsed ALL (where the leukaemia has come back) or refractory ALL (where the ALL did not respond to treatment).
- You will receive inotuzumab ozogamicin as an intravenous infusion over an hour. Your haematology team will supervise your inotuzumab ozogamicin administration in hospital.
- Administration of inotuzumab ozogamicin is for three or four cycles. You can have up to six cycles if you are not having an allogeneic stem cell transplant (allo-SCT). You may stop treatment earlier if your team believe inotuzumab ozogamicin is not working for you.
- Common side effects with inotuzumab ozogamicin are:
    - Low levels of platelets
    - Low levels of neutrophil white blood cells
    - Fever
    - Abnormal liver function
    - Diarrhoea
- If you experience these side effects, you should receive help to manage them. Speak to your haematology team if you are concerned about anything

Download our booklet on inotuzumab ozogamicin
Download our booklet on B-cell ALL

What is inotuzumab ozogamicin?

Inotuzumab ozogamicin is a treatment for some adults with acute lymphoblastic leukaemia (ALL). It is a monoclonal antibody linked to ozogamicin.

Inotuzumab ozogamicin sticks to CD22 proteins on leukaemia cells. CD22 proteins are present in 95% of immature B-ALL cells.

Once in the leukaemia cell, the ozogamicin part of inotuzumab ozogamicin causes severe damage to the DNA, leading to the death of the cell.

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Who might have it?

Patients who receive inotuzumab ozogamicin are:

- Adults with CD22-positive relapsed or refractory ALL
- Philadelphia chromosome-positive adults with relapsed or refractory ALL who have had previous unsuccessful treatment with at least one TKI.

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Before having this treatment

Your haematology team will perform an ECG on you before starting you on inotuzumab ozogamicin. This is important if you are also taking drugs known to prolong QT interval. Your haematology team will check your QT interval on a regular basis.

Inotuzumab ozogamicin can also be dangerous if your levels of immature leukaemia cells are too high. This is because it can be unsafe for you to have too many leukaemia cells dying at the same time. Dead cells release waste products that might overwhelm your kidneys and other organs if they reach high levels in your blood. This is called tumour lysis syndrome.

QT interval

Patients receiving inotuzumab ozogamicin show a lengthening of the QT interval. This can be seen on their electrocardiogram (ECG) tracing. A lengthening of the QT interval is a sign that the heart's electrical system is taking longer to recharge between heartbeats.

Your administration of inotuzumab ozogamicin will be monitored if you are taking drugs that are known to prolong the QT interval as well. These include the antidepressant citalopram and some antibiotics and antifungals.

Preventing tumour lysis syndrome

When the levels of leukaemia cells are too high, your haematology team may reduce them with other drugs first.

Recommended pre-medications before dosing with inotuzumab ozogamicin include:

- A corticosteroid, an antihistamine and a drug to prevent fever (e.g. paracetamol)
- Hydration and treatment to reduce uric acid levels, one of the waste products that leukaemia cells will create

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How do you have this treatment?

You have inotuzumab ozogamicin as an intravenous infusion over an hour. Your haematology team will supervise your inotuzumab ozogamicin administration in hospital. This is so any side effects that you experience can be managed. Some of the side effects of inotuzumab ozogamicin can be life-threatening.

You will also receive paracetamol, a steroid and an antihistamine. This will happen approximately 30 minutes before your infusion. This helps to reduce the risk of an infusion-related reaction.

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How many treatment cycles do you have?

You usually have inotuzumab ozogamicin for three or four cycles. You can have up to six cycles if you are not having an allogeneic stem cell transplant (allo-SCT). An allo-SCT is used to make sure you stay in remission if your ALL is considered high-risk.

Usually, inotuzumab ozogamicin is effective after three cycles. If it is not reducing the number of your leukaemia cells, your treatment will be reconsidered. The overall aim of treatment with inotuzumab ozogamicin is to get you back into complete remission.

You may stop inotuzumab ozogamicin treatment earlier if your team believe inotuzumab ozogamicin is not working for you.

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Monitoring

Your haematology team will monitor you for at least one hour after the end of your infusion. This is to check for any symptoms of infusion-related reactions. These include:

- Low blood pressure
- Hot flush
- Breathing problems

Infusion-related reaction

An infusion-related reaction is defined as a disorder due to an adverse reaction to the infusion of a drug. Infusion-related reactions occur in 10% of patients receiving inotuzumab ozogamicin.

If an infusion-related reaction occurs, your haematology team will start the following steps:

- Immediate interruption of the infusion
- Appropriate medical treatment

- Discontinuation of the infusion for the rest of the cycle if needed
- Administration of steroids and antihistamines for severe infusion-related reaction

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Precautions

There are no formal clinical drug interaction studies with inotuzumab ozogamicin.

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Fertility, pregnancy and breastfeeding

Inotuzumab ozogamicin is still a relatively new treatment, but its effects may be seen over time as it is used more.

Fertility and contraception

Inotuzumab ozogamicin may affect both male and female fertility, but there have not been any studies so far. It is also hard to separate the effects of inotuzumab ozogamicin from other treatments known to affect fertility. For example, you are likely to have already had chemotherapy.

You can seek advice for fertility preservation before treatment. Sometimes your treatment is too urgent to do this.

Pregnancy

Inotuzumab ozogamicin has not been studied in pregnant women. It is not recommended to take inotuzumab ozogamicin during pregnancy.

Breastfeeding

Inotuzumab ozogamicin has not been studied in women who are breastfeeding. But, given its mechanism of action, women should not breastfeed at the following times:

- During treatment with inotuzumab ozogamicin
- For at least two months after the final dose of inotuzumab ozogamicin

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Possible side effects

This is not a full list of all the side effects that can happen. The patient information leaflet in your medicine package has more information. Or you can find the leaflet in the Electronic Medicines Compendium.

Below are the most common side effects experienced by patients receiving inotuzumab ozogamicin. The percentages of patients affected by them are also included:

- Low levels of platelets (51% of patients)
- Low levels of neutrophils (49%)
- Infection (48%)
- Low levels of red blood cells (anaemia - 36%)
- Low levels of white blood cells (35%)
- Fatigue (35%)
- Haemorrhage (33%)
- Fever (32%)
- Nausea (31%)

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Serious side effects to be aware of

The most serious side effects with inotuzumab ozogamicin are:

- Infection (23% of patients)
- Febrile neutropenia (11%)
- Haemorrhage (5%)
- Fever (3%)

- Stomach pain (3%)
- Veno-occlusive disease (VOD - 2%)
- Tumour lysis syndrome (2%)

Veno-occlusive disease

Veno-occlusive disease (VOD) occurs in 2% of patients with B-cell relapsed or refractory ALL who are receiving inotuzumab ozogamicin. VOD is also called sinusoidal obstruction syndrome. It occurs when the small blood vessels in and around the liver become blocked.

VOD is more common in patients who undergo a stem cell transplant (SCT) after achieving remission with inotuzumab ozogamicin treatment. VOD develops in the first few weeks after a SCT and can be mild or severe.

Symptoms of VOD include:

- Jaundice (your skin and whites of the eyes become yellow and your urine is dark yellow)
- Liver tenderness (under the ribs on the right side of the body)
- Liver enlargement
- Ascites (abnormal build-up of fluid in the abdomen)
- Sudden weight gain

VOD damages cells in the liver, resulting in an obstruction that reduces blood flow in the liver. This can cause changes throughout the body that can lead to organ failure. Organs affected are the lungs, kidneys and brain.

It is important to recognise the symptoms of VOD early on because the condition can worsen quickly. Treatment of VOD includes supportive care, intensive care and specific treatment with defibrotide. The mechanism of defibrotide is not yet fully understood.

Tumour lysis syndrome

Tumour lysis syndrome occurs in 2% of patients with B-cell relapsed or refractory ALL taking inotuzumab ozogamicin. It may be life-threatening.

Tumour lysis syndrome occurs when large numbers of leukaemia cells die at the same time. On dying, leukaemia cells release uric acid, potassium and phosphorus into the blood. The levels of these waste products in the blood can get to higher levels than the kidney can cope with. This may result in damage to the kidney, but also the heart and liver.

Symptoms of tumour lysis syndrome include:

- Nausea and lack of appetite
- Vomiting
- Fatigue
- Low output of dark urine
- Pain in the side
- Numbness, seizures, or hallucinations
- Muscle cramps and spasms
- Heart palpitations

You will be monitored closely for tumour lysis syndrome and may be given drugs such as allopurinol or rasburicase to prevent it.

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What happens after treatment?

The aim of inotuzumab ozogamicin is to help you return to remission. If your treatment is successful, your leukaemia blood cell counts will eventually return to within normal ranges.

You might go straight into another treatment even if inotuzumab ozogamicin has worked for you. Your haematology team may use an allogeneic stem cell transplant if you are at high risk of relapse to make sure you stay in remission.

Adding a TKI may improve your complete remission if you are positive for the Philadelphia chromosome. This may improve the chances of remission compared to inotuzumab ozogamicin alone.

If inotuzumab ozogamicin has not worked for you, other treatment options may be available. They include:

- Blinatumomab
- CAR T-cell therapy

If you did not start your ALL treatment with chemotherapy, you may receive a combination of the following:

- Vincristine

- Daunorubicin or doxorubicin
- Cytarabine, either low dose cytarabine or higher dose cytarabine
- Asparaginase
- Etoposide
- Mercaptopurine
- Methotrexate
- Cyclophosphamide
- Steroids such as prednisone or dexamethasone

Other options include radiation therapy or an allogeneic stem cell transplant. Your consultant will be able to let you know of the best treatment for you going forward.

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Need support?

You are not alone. We're here for you whether you have a diagnosis yourself or know someone who has. If you'd like advice, support, or a listening ear, call our freephone helpline on 08088 010 444 or send a WhatsApp message to 07500 068 065.

Helpline and WhatsApp →

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