Patient agreement to systemic anti-cancer therapy (SACT)

Inotuzumab Ozogamicin for Relapsed or Refractory B Cell ALL

Hospital/NHS Trust/NHS Board:

_____

_____

Responsible consultant:

Name: _____

Job title: _____

Patient details

Patient's surname/family name:

_____

Patient's first name(s): _____

_____

Date of birth: _____

NHS number: _____
(or other identifier)

Special requirements:
(eg other language/other communication method)

_____

_____

_____

Name of proposed course of treatment (include brief explanation if medical term not clear)

☑ Inotuzumab Ozogamicin for relapsed or refractory Philadelphia chromosome positive* **OR** Philadelphia chromosome negative* B cell acute lymphoblastic leukaemia (ALL) (*delete as appropriate).

☑ Inotuzumab Ozogamicin is given intravenously on days 1, 8, 15 every 21 - 28 days (depending on response).

☑ **If proceeding to haematopoietic stem cell transplant (HSCT):** treatment is given for 2 - 3 cycles.

☑ **If not proceeding to haematopoietic stem cell transplant (HSCT):** treatment is given for up to 6 cycles.

Where will I have treatment?

☐ Outpatient ☐ Day unit/case ☐ Inpatient ☐ Other: _____

Statement of health professional

(to be filled in by health professional with appropriate knowledge of proposed procedure, as specified in the hospital/Trust/NHS board's consent policy)

☑ Tick all relevant boxes

☑ I confirm the patient has capacity to give consent.

☑ I have explained the course of treatment and intended benefit to the patient.

The intended benefits (there are no guarantees about outcome)

☐ Induction - to induce remission/control leukaemia before further treatment or stem cell transplant

☐ Improved survival

☐ Disease control/palliative - not to cure, but control disease and reduce symptoms, improving quality or quantity of life

Statement of health professional

Patient identifier/label

You may have one or more of the side effects listed

Common side effects:

Affecting more than 10 in every 100 (>10%) people

- ☑ Tiredness and feeling weak (fatigue), headaches.
- ☑ Sore mouth and ulcers, feeling sick (nausea), being sick (vomiting), tummy (abdominal) pain, diarrhoea, constipation.
- ☑ Reactions can happen while treatment is being given (during or shortly after the infusion has started), causing a fast heart rate, wheezing, flushing, face swelling, difficulty breathing, high or low blood pressure, a rash.
- ☑ Anaemia (low red blood cells) causing tiredness, low platelets causing bruising or bleeding. You may need a blood or a platelet transfusion.

Serious and important side effects:

- ☑ An increased risk of getting an infection from a drop in white blood cells - it is harder to fight infections and you can become very ill.
- ☑ **If you have a severe infection this can be life threatening. Contact your doctor or hospital straight away if:**
  - **your temperature goes over 37.5°C or 38°C, depending on the advice given by your chemotherapy team**
  - **you suddenly feel unwell (even with a normal temperature)**

Rarer and organ specific side effects:

- ☑ Liver effects range from minor changes in how well the liver works to a blockage in the veins in the liver (veno-occlusive liver disease, which can be life-threatening). Tell your doctor if you have appetite loss, feeling or being sick, diarrhoea, dark-coloured urine, light-coloured stools, tummy pain, yellowing skin or eyes, feeling generally unwell, rapid weight gain, fluid build-up causing swelling.
- ☑ Veno-occlusive liver disease may happen during treatment, but also at a later stage if you are having a stem cell transplant.

Other risks:

- ☑ An increased risk of tumour lysis syndrome (when treatment destroys cancer cells too quickly for the kidneys to cope). Rarely, kidney dialysis may be needed. You may be prescribed medicines for prevention.
- ☑ Before treatment, you might have blood tests to check for viruses such as Hepatitis B, Hepatitis C, HIV or more unusual infections. This treatment can cause your natural defence (immune) system to be less effective, making you prone to infections. Existing infections could worsen or become active again if you've had them in the past. You may have medicines to prevent or treat infection.
- ☑ All intravenous drugs may leak outside of the vein and damage the tissue around it while being given (extravasation). Tell the nurse straight away if you have any stinging, pain, redness or swelling around the vein . It's uncommon, but important to deal with quickly.
- ☑ Cancer and its treatment may increase your risk of developing a blood clot (thrombosis), causing pain, redness and swelling in an arm or leg, breathlessness, chest pain or a stroke. Tell your doctor straight away if you have any symptoms.
- ☑ Some anti-cancer medicines can damage ovaries and sperm. This may lead to infertility and/or early menopause.
- ☑ Some anti-cancer medicines may damage the development of a baby in the womb. It is important not to become pregnant or make someone else pregnant during treatment and for 12 months afterwards. Use effective contraception during this time.
- ☑ Complications of treatment can be life threatening and may result in death. The risks are different for every individual. Potentially life threatening complications include those listed on this form, but, other exceedingly rare side-effects may also be life threatening.

Statement of health professional

Patient identifier/label

Any other risks and information:

_____

_____

☑ I have discussed the intended benefit and risks of the recommended treatment, and of any available alternative treatments (including no treatment).

☑ I have discussed the side effects of the recommended treatment, which could affect the patient straight away or in the future, and that there may be some side effects not listed because they are rare or have not yet been reported. Each patient may experience side effects differently.

☑ I have discussed what the treatment is likely to involve (including inpatient/outpatient treatment, timing of the treatment, blood and any additional tests, follow-up appointments etc) and location.

☑ I have explained to the patient, that they have the right to stop this treatment at any time and should contact the responsible consultant or team if they wish to do so.

☑ I have discussed concerns of particular importance to the patient in regard to treatment

(please write details here): _____

_____

Clinical management guideline/Protocol compliant (please tick):

☐ Yes ☐ No ☐ Not available If No please document reason here:

_____

The following written information has been provided:

☑ Information leaflet for Inotuzumab Ozogamicin

☑ 24 hour alert card or SACT advice service contact details

☑ SACT treatment record (cruk.org/treatment-record)

☐ Other, please state: _____

_____

Health professional details:

Signed: _____

Date: _____

Name (PRINT): _____

_____

Job title: _____

_____

Statement of interpreter **(where appropriate)**

Interpreter booking reference (if applicable):

I have interpreted the information above to the patient to the best of my ability and in a way in which I believe they can understand.

Signed: _____ Date: _____

Name (PRINT): _____ Job title: _____

Statement of patient

Patient identifier/label

Please read this form carefully. If your treatment has been planned in advance, you should already have your own copy of the form which describes the benefits and risks of the proposed treatment. If not, you will be offered a copy now. If you have any further questions, do ask – we are here to help you. You have the right to change your mind at any time, including after you have signed this form.

☐ I have had enough time to consider my options and make a decision about treatment.

☐ I agree to the course of treatment described on this form.

A witness should sign below if the patient is unable to sign but has indicated their consent. A person with parental responsibility will be asked to sign for young people under the age of 16 years.

Patient's signature: _____

Name (PRINT): _____ Date: _____

Person with parental responsibility/witness' signature: _____

Name (PRINT): _____ Date: _____

Copy accepted by patient: yes / no (please circle)

Confirmation of consent

(health professional to complete when the patient attends for treatment, if the patient has signed the form in advance)

On behalf of the team treating the patient, I have confirmed that the patient has no further questions and wishes the course of treatment/procedures to go ahead.

Signed: _____

Date: _____

Name (PRINT): _____

Job title: _____

Important notes: (tick if applicable)

☐ See also advance decision to refuse treatment

☐ Patient has withdrawn consent (ask patient to sign and date here)

Signed: _____

Date: _____

Further information for patients

Contact details (if patient wishes to discuss options later):

_____

Contact your hospital team if you have any questions about cancer and its treatment.

Cancer Research UK can also help answer your questions about cancer and treatment. If you want to talk in confidence, call our information nurses on freephone 0808 800 4040, Monday to Friday, 9am to 5pm. Alternatively visit cruk.org for more information.

These forms have been produced by Guy's and St. Thomas' NHS Foundation Trust as part of a national project to support clinicians in ensuring all patients are fully informed when consenting to SACT.

The project is supported by Cancer Research UK. This does not mean you are taking part in a clinical trial.

Guidance for health professionals

(to be read in conjunction with the hospital's consent policy)

Patient identifier/label

What a consent form is for

This form documents the patient's agreement to go ahead with the treatment you have proposed. It is not a legal waiver – if patients, for example, do not receive enough information on which to base their decision, then the consent may not be valid, even though the form has been signed. Patients are also entitled to change their mind after signing the form, if they retain capacity to do so. The form should act as an aide-memoir to health professionals and patients, by providing a checklist of the kind of information patients should be offered, and by enabling the patient to have a written record of the main points discussed. In no way should the written information provided for the patient be regarded as a substitute for face-to-face discussions with the patient.

The law on consent

See the following publications for a comprehensive summary of the law on consent. Consent: Patients and doctors making decisions together, GMC 2020 (gmc-uk.org/guidance). Reference guide to consent for examination or treatment, Department of Health, 2nd edition 2009 (doh.gov.uk).

Who can give consent

Everyone aged 16 or over is presumed to have the capacity to give consent for themselves, unless the opposite is demonstrated. For young people, it is good practice to involve those with parental responsibility in the consent discussions, unless specifically asked not to. A person with parental responsibility must sign this form for a child or young person under the age of 16. Such patients should be given the opportunity to 'assent' to treatment if they wish. If a patient has the capacity to give consent but is physically unable to sign a form, you should complete this form as usual and ask an independent witness to confirm that the patient has given consent orally or non-verbally.

When NOT to use this form

If the patient lacks the capacity to give consent, you should use an alternative form available for this purpose (dependent on patient age). A patient lacks capacity if they have an impairment or disturbance of the brain, affecting the way their mind works. For example, if they cannot do one of the following:

- understand information about the decision to be made
- retain that information in their mind
- use or weigh this information as a part of their decision making process, or
- communicate their decision (by talking, using sign language or any other means)

You should always take all reasonable steps (for example involving more specialist colleagues) to support a patient in making their own decision, before concluding that they are unable to do so. Relatives cannot be asked to sign a form on behalf of an adult who lacks capacity to consent for themselves, unless they have been given the authority to do so under a Lasting Power of Attorney or as a court deputy.

Information

Information about what the treatment will involve, its benefits and risks (including side-effects and complications) and alternatives to the particular procedure proposed, is crucial for patients when making up their minds. The courts have stated that patients should be told about 'significant risks which would affect the judgement of a reasonable patient'. 'Significant' has not been legally defined, but the GMC requires doctors to tell patients about 'significant, unavoidable or frequently occurring' risks. If patients make clear they have particular concerns about certain kinds of risk, you should ensure that they are informed about these risks, even if very small or rare. You should always answer questions honestly. Sometimes, patients may make it clear that they do not want to have any information about the options, but want you to decide on their behalf. In such circumstances, you should do your best to ensure that the patient receives at least very basic information about what is proposed. Where information is refused, you should document this on the consent form or in the patient's notes.

NHS Scotland

NHS Scotland staff should refer to Healthcare Improvement Scotland. Guidance on consent for SACT and local NHS Board guidance on consent aligned to the Scottish legal framework.

References

1. Summary of Product Characteristics for individual drugs: medicines.org.uk/emc
2. Cancer Research UK: cruk.org/about-cancer/treatment/drugs
3. Macmillan Cancer Support: macmillan.org.uk/cancer-information-and-support/treatments-and-drugs
4. Guy's and St. Thomas' NHS Foundation Trust, Chemotherapy consent form