Patient agreement to systemic anti-cancer therapy (SACT)

Gemtuzumab ozogamicin with Daunorubicin and Cytarabine

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)

- ☑ Gemtuzumab, Daunorubicin and Cytarabine for the treatment of CD33 positive acute myeloid leukaemia (AML).
- ☑ Induction 1: Gemtuzumab given intravenously on days 1,4 &7, Daunorubicin intravenously on days 1 to 3, Cytarabine intravenously on days 1 to 7.
- ☑ Induction 2 (only if needed): Daunorubicin on days 1 & 2. Cytarabine on days 1 to 3.
- ☑ Consolidation 1: Gemtuzumab on day 1, Daunorubicin on day 1, Cytarabine on days 1 to 4.
- ☑ Consolidation 2: Gemtuzumab on day 1, Daunorubicin on days 1 & 2, Cytarabine on days 1 to 4.

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)

- ☐ Prolong survival.
- ☐ Control symptoms, reduce transfusion needs and improve quality of life.
- ☐ Induction – therapy given in the acute state of the disease, aiming to shrink the tumour.
- ☐ Curative – to give you the best possible chance of being cured.
- ☐ Maintenance – therapy given on continuing basis, aiming to prevent disease flaring up and to control the symptoms.
- ☐ Disease control / Palliative – the aim is not to cure but to control the disease and reduce the symptoms. The aim is to improve both quality and 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

- ☑ An increased risk of getting an infection from a drop in white blood cells - this makes it 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 over 38°C, depending on the advice given by your chemotherapy team**
  - **you suddenly feel unwell (even with a normal temperature)**
- ☑ Nausea (feeling sick), vomiting (being sick), abdominal (tummy) pain, indigestion, constipation, diarrhoea.
- ☑ Sore mouth and ulcers, loss of appetite, difficulty swallowing, taste changes, feeling weak and tired (fatigue).
- ☑ Thinning of the hair or hair loss, skin changes (itching, rash, darkening), change in nail colour.
- ☑ Anaemia (due to low red blood cells) and bruising or bleeding (due to low platelets); this can be prolonged and you may need a transfusion, changes in liver and kidney function (monitored).
- ☑ You may have nose bleeds, bleeding gums, blood in the urine, stools or tiny red, brown or purple spots that may look like a rash.
- ☑ Red colour urine for 1-2 days after treatment (due to daunorubicin).
- ☑ Headache, fluid build-up in hands and feet, rash, high or low blood pressure, high heart rate, shortness of breath, chills.
- ☑ Inflammation of the lining of the eye lids (conjunctiva) making eyes feel sore, red and itchy (this is temporary). Steroid eye drops during and for 3 days after Cytarabine to prevent this will be given.
- ☑ Gemtuzumab ozogamicin can raise your blood sugar. If you have diabetes, it may lead to higher blood sugar levels.
- ☑ Cytarabine syndrome can occur 6 to 12 hours after receiving Cytarabine. Symptoms include a high temperature or chills, rash, pain in the eyes, bones, tummy and chest. Inform your doctor or nurse.

Occasional side effects:

Affecting between 1-10 in every 100 (1-10%) people

- ☑ Liver related side effects from minor through to veno-occlusive disease which can be potentially life-threatening. Let your doctor or nurse know if you experience rapid weight gain, pain in the upper right side of your belly, jaundice (yellow skin), build-up of fluid around your tummy.
- ☑ Infusion related side effects may occur during or shortly after the infusion. Symptoms include fast heart rate, wheezing, face swelling, difficulty breathing, fluctuating blood pressure and rash.
- ☑ Inflammation and ulcers at the opening end of the bowel (anus), which can be severe leading to infections.
- ☑ Heart problems with changes in the way your heart works including abnormal heart rhythm (fast heart rate) and risk of a heart attack.
- ☑ Severe skin changes (redness, itching sometimes blisters), acid reflux, weight loss.
- ☑ Eye sight changes (reversible), high uric acid levels.
- ☑ One or more of your organs may not work properly (this can be life-threatening).
- ☑ High dose Cytarabine can cause temporary or occasionally permanent changes to the nervous system. Symptoms include seizures (fits), drowsiness, unsteadiness and mood changes.
- ☑ There may be an increased risk of tumour lysis syndrome in some patients (when treatment destroys cancer cells too quickly for the kidneys to cope and leads to changes in blood tests. Rarely, dialysis may be needed. You may be prescribed medicines for prevention or treatment.

Other risks:

- ☑ All intravenous drugs may leak out of the vein while it is being given (extravasation) and can damage the tissue around the vein. 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.
- ☑ Also, rarely high dose Cytarabine can cause changes in the lungs with shortness of breath, wheeezing, cough or a fever. Please inform your doctor or nurse if you notice these symptoms.
- ☑ Side effects with the anti-sickness medication may include: constipation, diarrhoea, headaches.

Continue on to the next page

Statement of health professional

Patient identifier/label

Other risks continued:

- ☑ Before treatment you may have blood tests to check for viruses (Hepatitis B or C, HIV, or unusual infections). Treatment may weaken your natural defence (immune) system so infections like this may worsen or become active if you've had them before. You may have medicines to prevent or treat infection.
- ☑ Growth factors (GCSF) may be prescribed to maintain number of white cells to prevent infection. You may experience bone pain, headaches, red and itchy skin around the injection site.
- ☑ Late effects include a rare chance of a second cancer (years later) and problems with your heart.
- ☑ Changes in your memory, concentration or ability to think clearly. There can be many causes including your treatment, diagnosis, or both.
- ☑ Cancer and its treatment can increase your risk of developing a blood clot (thrombosis), causing pain, redness and swelling in an arm or leg, breathlessness, chest pain. 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 (hot flushes, vaginal dryness).
- ☑ 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 up to 7 months afterwards. It is advisable to use 2 methods of effective contraception during treatment with Gemtuzumab ozogamicin. Women of child bearing age will be tested for pregnancy before and during treatment. Use effective contraception throughout. Speak to your doctor or nurse.
- ☑ Complications of treatment can very occasionally 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:

_____

_____

- [x] I have discussed the intended benefit and risks of the recommended treatment, and of any available alternative treatments (including no treatment).
- [x] 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.
- [x] 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.
- [x] 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.
- [x] 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 b

- [x] Information leaflet for Gemtuzumab ozogamicin, Daunorubicin and Cytarabine
- [x] 24 hour alert card or SACT advice service contact details
- [x] 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