
1 Why we are doing this study

This trial is for people with one of 2 types of cancer of the bone marrow:

- Acute Myeloid Leukaemia (AML)
- Myelodysplasia (MDS)

The trial will compare one of the standard non-intensive treatments (Low Dose Cytarabine) with three other medicines. It will also look at any side effects of the medicines.

What happens in these cancers?

In both types of cancers, the bone marrow cannot make enough blood cells (red cells, white cells and platelets). This is because the marrow contains too many leukaemia cells. If you want to know more about these illnesses, talk to people in your Haematology team.

What are the two main types of treatment?

There are two main ways of treating AML in older patients. The first of these (intensive treatment) is with medicines (chemotherapy). The idea of this treatment is to get rid of the leukaemia completely. The second way (non-intensive treatment) is also to use medicines (chemotherapy), but which have a lower chance of getting rid of the leukaemia. This is usually suitable for patients who may not be able to withstand the more intensive treatment, or who do not want it. Patients having non-intensive treatment do not need to be in hospital so often.

The aim of both intensive and non-intensive treatments is to kill the leukaemia cells and allow the bone marrow to work normally again. This stage is called 'disease remission'. The two types of treatment are:

- **Intensive Treatment** - involves coming into hospital 2 to 4 times and having chemotherapy by injection. This is usually as an in-patient. This approach usually leads to disease remission, but has some risks.
 - It is suitable for people who are more fit.

- **Non-Intensive Treatment** - involves less time in hospital. Some of the medicines can be taken by mouth and as an out-patient. The medicines are used to control the leukaemia cells in the bone marrow, rather than to try to get rid of them completely. This means it is less likely to cause complete disease remission.
 - It is more suitable for people who are less fit, or have other illnesses.

If you want to know more about these two treatments, talk to people in your Haematology team.

Your doctor has discussed these two treatments with you. As a result it was decided that you will have the '**non-intensive**' treatment.

If you decide not to enter this trial, you are likely to receive the standard non-intensive treatment, which is up to four courses of Low Dose Cytarabine (see Section 4), or a medicine called Hydroxyurea (given by mouth).

The rest of this leaflet is about the non-intensive treatment given within the trial.

2 Why am I being asked to take part?

Your doctor has found that you have AML or MDS. This needs treatment with non-intensive chemotherapy. Treatments for patients getting non-intensive chemotherapy need to be improved. New treatment options have become available which will be tested in this trial'.

3 What do I need to know about the medicines used in this study?

One of the standard treatments at the moment is a medicine called Cytarabine. It is given in low doses. This treatment is called 'Low Dose Cytarabine'.

This research trial is aimed at testing three new medicines, used together. The three medicines are:

- Clofarabine
- Mylotarg
- Trisenox.

These medicines have already been given to patients separately.