

Introduction

As a parent or legal guardian, you have the right to be informed about the benefits and risks of the cytostatic treatment of malignant processes in children (CHEMOTHERAPY) as we propose for your child.

It is a rule to inform you and ask for your authorisation as long as this is permitted by the urgency of the case.

1. Identification and description of the procedure

Your child or the person you are representing has been diagnosed by our unit with _____. This is a malignant illness the treatment and prognosis of which is influenced by a number of factors which will be explained to you in detail by the paediatric oncologists in charge of the treatment.

The main pillars of cancer treatment are: Surgery, radiotherapy and CHEMOTHERAPY. The suitability of each of these treatments and its use or not for this specific illness will be explained to you by the professionals in charge at the time, and where applicable, your authorisation for the procedure to go ahead will be requested.

CHEMOTHERAPY consists in intravenously administering cytostatic drugs (i.e. drugs which prevent cells from reproducing). The drugs which are administered to each child depend on the diagnosis and the extent of the illness, and in the vast majority they fall within national and international treatment protocols which are widely accepted by the scientific community.

2.- Purpose of the procedure and expected benefits

Chemotherapy acts by attacking the tumour cells with the aim of preventing them from growing locally, spreading to other vital organs and in specific cases, the aim is to make tumours operable which at outset are not in view of their size or location. The purpose of this treatment is, therefore, to increase the chances of completely removing the illness which the patient is suffering from. We therefore hope to improve the chances of curing the illness or achieving a considerable long-term life expectancy.

3.- Reasonable alternatives to this procedure

Some paediatric tumours can be cured by surgery alone. Unfortunately, the majority of children with cancer require more aggressive treatments and at present there are no alternatives to chemotherapy which achieve similar levels in curing the illness.

4.- Predictable consequences of the procedure

Chemotherapy can cure oncological illnesses or achieve an extended life expectancy.

5.- Predictable consequences if not performed

The most common cancers that occur in children are highly aggressive. Without suitable treatments, among which chemotherapy is one, they are terminal in the short-term.

6.- Risks

Cytostatic drugs have shown themselves to be a powerful therapeutic resource against the illness affecting your child given that they are aimed at damaging tumour cells, hence their medical use. However, they are unfortunately also capable of damaging healthy cells in the body. For this reason, it can be expected that some undesired effects will arise from their use, the so-called side effects of chemotherapy, which you should have knowledge of:

Some appear soon:

Being directly linked to the application of the drug, their appearance can be expected just over the days on which the cycle is being administered, and will gradually disappear during periods of rest.

They tend to be common but not serious, of little intensity and are well tolerated thanks to the support measures we have access to. They consist of gastrointestinal problems (vomiting, loss of appetite, abdominal pains), and others such as change of mood, muscular pains, skin reactions, fever. Some are related to the intravenous administration of drugs (inflammation of the vein, lesions in surrounding tissues).

Others appear as the treatment continues:

In general over the days following each cycle. The most common are as follows: Hair loss, though the hair usually returns once the treatment is completed, and bone marrow toxicity, which is temporary and recovers in a few days. One of the functions of bone marrow is the production of important blood cells: red blood cells (a fall in their numbers causes anaemia), platelets (which enable the blood to coagulate and not haemorrhage) and leucocytes (which defend the body from infections). Whilst the bone marrow is affected, there may be a considerable fall in the number of these three types of cell, and this may mean that a blood or platelet transfusion is necessary. If this need arises you will be duly informed. With regard to a fall in the number of leucocytes, infections may arise against which support measures are used. These may include antibiotics. In spite of this, these infections may sometimes be very serious and put the patient's life at risk.



Cytostatic treatment in malignant processes in children (Chemotherapy)

Others appear much later as "consequences" of the treatment:

These arise from the specific toxicity of the cytostatic drugs on specific sensitive organs. Preventative measures which are used during treatments help to prevent these consequences together with continuous clinical tests and analyses and subsequent monitoring, over many years, in the unit's outpatient centre.

Most exceptionally a second malignant tumour, different from the first one, may appear years after the treatment which may be linked to the use of chemotherapy.

There is a risk that the illness will not respond sufficiently to the treatment, or that there could be a relapse during treatment or once it has ended.

7.- Risks depending on the patient's clinical situation

Before starting the oncological treatment, the paediatrician will carefully assess the child's clinical state in order to identify any possible pathologies which would make the treatment inadvisable. Each case is assessed specifically.

Declaration of consent

Mr./Mrs./Miss. aged , with home address at
..... , National Identity No. and SIP number
.....

Mr./Mrs./Miss. aged , with home address at
..... acting in the capacity of (the patient's legal representative, relative or close
friend) , with National Identity No.

Hereby declare:

That the Doctor has explained to me that it is advisable/necessary in my
situation to perform a
.....
and that I have adequately understood the information he/she has given me.

In on , 2

Signed: Mr./Mrs./Miss. With National Identity Card No

Signed: Dr. With National Identity Card No

Associate number

Revocation of the consent

I hereby revoke the consent granted on the date of , 2 and I do not wish
to carry on with the treatment that I hereby terminate on this date.

In on , 2

Signed: The Doctor

Signed: The patient

Associate number:

