



Content of Attach H – **POSSIBLE RISKS OF HEMATOPOIETIC STEM CELL (HSC) DONATION**

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This document is not intended in substitution Attach B but as a possible support. **It is reminded that under Italian current legislation the potential blood stem cell donor must be able to understand (including forms) and communicate in Italian.**

HPC donation from bone marrow

The risks for donation from bone marrow are mainly classified in the following four items:



1. Anesthesia risks

The anesthesia risks are due to the type of anesthesia given, to the procedure adopted and to the anesthetic agents used.

Very rare complications are due to the intravenous infusion procedure, to the endotracheal intubation or to the lumbar injection.

The anesthetic agents used can give allergic reactions, such as idiosyncratic or hypersensitivity reactions related to specific agents. Some of them can be serious or fatal reactions (1:35.000).

2. Infection risk

The sites of bone marrow collection and the sites of injections in rare cases can be infected.

Some infectious diseases can also be observed in other sites, such as pulmonary infections.

The infectious diseases, in some cases, must be treated with antibiotics. These medicines can give allergic reactions, such as idiosyncratic or hypersensitivity reactions related to specific drugs. Some infectious diseases or some reactions due to their pharmacological treatment can be serious or fatal reactions. (Infectious diseases requiring an antibiotic treatment are reported in 0,1% of cases).

3. Risk of injury

The procedure adopted for the collection of bone marrow can cause injuries to the tissues involved. These can include lesions to the bone or to a nerve, or perforation, of a blood vessel or of an organ with the bone marrow collection needle. Such injuries can make necessary further treatment and / or surgery, which can be immediate or delayed. Some of these damages or their subsequent treatment can also be very serious or even fatal. (3% of the donors complained back pain, sciatica even after some time).

4. Blood transfusion risk

According to IBMDR Standards, during the collection of bone marrow, the donor receives autologous blood units, previously donated; only in very rare cases of proven emergency, it can

be necessary to transfuse the donor with allogeneic blood. From autologous donation the related risks (allergic reactions or transmission of infectious diseases) are very rare. Anyway the blood transfusion complications can be very serious.

In general, the risk of adverse events unfavorable after donating HSC from bone marrow is 0.15%. (Source register SEAR 2008 World Marrow Donor Association)

HPC donation from peripheral blood

The risks of peripheral blood stem cells (PBSC) donation are mainly classified in the following four items:



1. Drug hypersensitivity

Some individuals may experience hypersensitivity to the drug (growth factor) given before mobilization or to its excipients. In this case, the administration should be stopped.

2. Mobilization and collection risks

The collection of HSC after stimulation with growth factors is a nonsurgical procedure, called apheresis, in which is used an anticoagulant solution (Anticoagulant Citrate Dextrose - ACD). ACD can give tingling sensation in the fingers, nose and, rarely, muscle contractions. Such reactions can be overcome with intravenous administration of calcium. The mortality risk associated with the mobilization and the collection of PBSC (cerebrovascular accidents, broken spleen and myocardial ischemia) in healthy subjects (younger than 55 years) is very low. There is no evidence, to date, to consider the PBSC collection risk major than the marrow collection risk.

3. Infection risk

The sites of blood collection in rare cases can be infected. The infectious diseases, in some cases, must be treated with antibiotics. These medicines can give allergic reactions, such as idiosyncratic or hypersensitivity reactions related to specific drugs. Some infectious diseases or some reactions due to their pharmacological treatment can be serious or fatal reactions. (Infectious diseases requiring an antibiotic treatment are reported in 0,1% of cases).

5. Risk of injury

After administration of the growth factor, very rare cases of spleen rupture or increased spleen size have been registered in healthy donors. Initial symptom of this adverse event is pain in the left upper abdominal or shoulder. Such injuries can make necessary further treatment and / or surgery, which can be immediate or delayed. Some of these damages or their subsequent treatment can also be very serious or even fatal.

In general, the risk of adverse events unfavorable after donating HSC from peripheral blood is 0.20%. (Source register SEAR 2008 World Marrow Donor Association)

Main side effects observed in the two types of donation

Bone marrow donation		PBSC donation	
Symptom	Percentage of donors who reported the side effect*	Symptom	Percentage of donors who reported the side effect**
Tiredness	80%	Bone pain	96%
Pain in the area of the collection	75%	Headache	78%
Pain in walking	71%	Myalgia	78%
Back ache	65%	Feeling of general discomfort	78%
Sore throat	60%	Insomnia	41%
Pain in sitting	59%	Nausea	33%
Pain in climbing stairs	50%	Flu-like symptoms	33%
Nausea	50%	Increased sweating	25%
Mild headache	45%	Anorexia	21%
Headache	35%	Chills	19%
Pain in the lumbar	29%	Fever	16%
Vomit	27%	Local reactions at the injection site	12%
Pain in the area of bandage	23%	Skin reactions	9%
Fever	22%	Vomit	8%
Haemorrhage at the collection sites	9%	Allergy	3%
Weakness	4%		

* **Source:** Data collected from the registry of bone marrow donors USA -NMDP from 11,084 subjects unrelated who donated bone marrow HSCs from 1989 to 2002;

****Source:** Data collected from the registry of bone marrow donors -NMDP USA between 1999 and 2001 of 395 unrelated individuals who donated PBSC.