

SHEFFIELD CLINICAL IMMUNOLOGY AND ALLERGY SERVICE

Sheffield Teaching Hospitals 
NHS Foundation Trust

These constitute guidelines for the diagnosis/management of the condition stated, for use by immunology doctors and nurses within the Sheffield Clinical Immunology and Allergy Service.

Clinical judgement supersedes these guidelines whenever necessary.

PATIENT INFORMATION:

HYPOGAMMAGLOBULINAEMIA: INTRAVENOUS IMMUNOGLOBULIN (IVIG) TREATMENT

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Who can use this Leaflet?

CIAU Staff

When to use this leaflet?

To Inform patients or medical/nursing staff of the benefits and risks of IVIG therapy during initial risk counselling, prior to obtaining consent

Hypogammaglobulinaemia: Intravenous Immunoglobulin (IVIg) Treatment

- Individuals may have low antibody levels for many different reasons. The doctor will have discussed the ones involved in you/your child's particular situation with you.
- This information sheet concerns the treatment of individuals with hypogammaglobulinaemia rather than the cause of the disease.

Who needs treatment?

- The current treatment for most people with low antibody levels is to give them antibodies obtained from the blood of healthy normal people.
- This is the treatment of choice in people with a significant antibody deficiency.
- Some people may only have a selective lack of certain antibodies (i.e. IgG subclass deficiency or a specific antibody deficiency against certain bacteria). In such cases some people may benefit from immunoglobulin treatment, but others may not. The doctor will discuss other treatment plans with these individuals (which may include immunisation and preventative antibiotic treatment) and, if these are not effective, then consider a trial of immunoglobulin treatment.
- Other strategies of treatment are being developed.

What is the treatment?

- Antibodies are obtained from blood given by healthy normal people.
- To make sure that the treatment contains antibodies against a wide range of infections, and therefore be of most benefit to a person with an inability to make some or all antibodies, antibodies are obtained from the blood of a large pool of people.
- The antibodies are separated from the rest of the blood by a series of important processes.

How is the treatment given?

- The immunoglobulin (antibody) treatment comes as either a liquid, or a powder which needs to be dissolved in water, and is given into a vein through a drip.
- It takes 3-4 hours to give the treatment, which is initially given in hospital. Later, some people may be able to give themselves / their child the treatment at home, and this will be discussed with you by the doctor and specialist nurse.
- Most people need treatment every 3 weeks, but some people need this every 2 weeks and others only need treatment every 4 weeks.
- Treatment needs to be given more frequently at the start to build up the antibody levels. It will be given every 1-2 weeks for 3-6 weeks depending on your / your child's need.

Could there be any problems?

- Yes, but very rarely.
- A few people can get severe reactions to the immunoglobulin treatment, which is why it is always initially given in hospital by a specialist nurse and doctor. If a reaction should occur, appropriate treatment can be given immediately.
- If blood from even one person with an infection formed part of the pool, it would contaminate the whole pool. HIV and hepatitis are amongst the infections that are a potential problem, and both the manufacturers of the treatment and the doctors are aware of this. You may remember that some patients with haemophilia (a different problem) were infected with the HIV virus in the mid-1980s before this was a recognised problem. Regrettably, in 1994 a few patients with antibody deficiency were infected with the hepatitis C virus, but we no longer use this make of immunoglobulin. A range of steps is now in place to help minimise this risk.

How is viral transmission avoided?

- The people who donate blood are screened for certain viral infections known to be transmitted by blood transfusion (i.e. HIV, hepatitis B and hepatitis C) by testing for antibodies to the virus or for the virus itself.
- People who have received a blood transfusion are excluded from donation to reduce the risk of transmission of viral infections, as are people who have had or are at risk of certain infections.
- Blood donors also have their liver function tests checked, because there are some hepatitis viruses which cannot be identified at present, but which can cause abnormal liver function tests. The blood of any person with an abnormal liver test is excluded from the pool.
- Some companies which make the immunoglobulin treatment also only take blood from donors they have known for a long time, and therefore will have documented normal tests over an extended time period.
- The basic manufacturing process used by all companies which make immunoglobulin treatment are known to kill most viruses. Some viruses, such as the HIV virus, are relatively easily killed by such processes.
- Other viruses, such as the hepatitis C virus, are more difficult to kill, and other steps which are known to kill such viruses are included in the manufacturing process. These steps vary from company to company, but all the immunoglobulin treatment used in this hospital incorporates at least one of these other viral killing steps in its manufacturing process.
- The final immunoglobulin product is also directly checked for viruses to ensure that the manufacturing processes have not failed. This has only recently been introduced (1994).
- The doctors review the different immunoglobulin preparations available, their safety record, and details of their manufacturing processes (as confidentially provided by the company) in deciding which immunoglobulin products to recommend and use.
- As yet, no cases of new variant Creutzfeld Jakob disease (nvCJD) have been transmitted through immunoglobulin treatment. Experiments have shown that the liquid part of blood donations used to make immunoglobulin products is much less likely to contain the infectious agent compared to cells or tissues. We therefore believe that the risk of transmitting nvCJD through immunoglobulin is extremely small.

Final comment

- We do not wish to put you off immunoglobulin treatment, with its proven benefit for your health, but feel that you should appreciate the potential problem from certain infections, and the steps that are taken to make these risks very small.
- The risk may not be the viruses we know about (and can test for) today, but those which are discovered in the future. To make the immunoglobulin treatment as safe as possible, the manufacturing processes which are designed to kill viruses are tested against both viruses that we know are hard to kill as well as those which are easy to kill.