VCH Diagnostic Imaging, MRI
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DRAFT

INFORMED CONSENT

USE OF A GADOLINIUM CONTRAST AGENT FOR MRI EXAMINATIONS IN PATIENTS WITH RENAL IMPAIRMENT OR LIVER TRANSPLANT

BACKGROUND

Your informed consent is being requested because you are a patient with renal impairment (your kidneys are not working normally) or liver transplant, and you have an additional serious illness. Your doctors believe it is in your best interest to have an MRI (magnetic resonance imaging) examination that includes the intravenous or IV injection (through an arm or hand vein) of a contrast agent containing gadolinium.

Gadolinium-containing contrast agents are given during MRI examinations to provide additional information regarding the presence and extent of inflammation, infection, or tumours, and to evaluate blood vessels. Gadolinium has been considered to be quite safe, with a very low risk of minor allergic reactions, and an extremely low risk of serious allergic reactions.

It has recently come to light, however, that the use of gadolinium in patients with renal impairment or liver transplant may be associated with a condition called Nephrogenic Systemic Fibrosis (NSF). This is a condition that results in deposits of fibrous scar-like tissue in and underneath the skin, usually of the arms and legs. It is usually limited to the skin, but can involve the muscles. The skin and muscles may feel thickened, woody, and painful. Other symptoms may include red or dark patches on the skin and persistent itchiness. This may result in the inability to straighten the elbow, hip or knee joints. Uncommonly this scar-like tissue can involve the heart, lungs, kidneys and other organs, and it can cause death. The great majority of cases of NSF have been associated with severe degrees of renal impairment, with one particular gadolinium preparation, and with higher doses of this particular preparation. The absolute risk of developing this disease varies considerably amongst patient groups, but may be up to 1-5% in those patients with advanced renal disease.

The condition usually develops two weeks to several months following exposure to gadolinium. At present there is no effective way of treating this condition if it develops.

IS THERE ANY POTENTIAL BENEFIT TO ME IF I RECEIVE GADOLINIUM?

You have a serious medical condition that your doctors believe poses a significant threat to your life, your future health, or may lead to loss of a limb. Despite the risk of developing NSF, your doctors believe that an MRI examination with gadolinium is the best way to obtain essential information that will help them to provide you with the best medical care possible.

IS THERE ANY WAY OF PROTECTING ME FROM DEVELOPING NSF?

If you agree to receive gadolinium, it will be given to you in the lowest dose possible that will provide the information required. We will use the safest form of gadolinium available, based on current information.

Vancouver Coastal Health
Promoting wellness. Ensuring care.

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Although we believe that these measures may provide some protection, there is no proof that these actions will prevent NSF.

CONSENT

I have read and understand the above information, and have had an opportunity to have my questions answered.

I will receive a copy of this consent form.

I am a patient with renal impairment or a liver transplant, and an additional serious medical condition. I agree to receive an intravenous injection of a contrast agent containing gadolinium as part of an MRI examination to provide further information regarding this additional condition. If I develop any of the symptoms listed on the previous page, I will contact my physician immediately.

_____ _____

Patient signature Date

_____ _____

Proxy signature and relationship to patient Date

_____ _____

Witness signature Date

Revised June 5, 2007