# Information for Health Care Professionals

## What is Metabolic Neuromodulation Therapy

This is a new therapy with the potential to reduce high blood sugar levels in type 2 diabetes. This one-time procedure involves passing a catheter through the femoral artery in the right groin into the hepatic artery. Radiofrequency energy is then passed through the end of the catheter into the hepatic artery and has the effect of disrupting and scarring the adjacent nerves that lead to the liver.

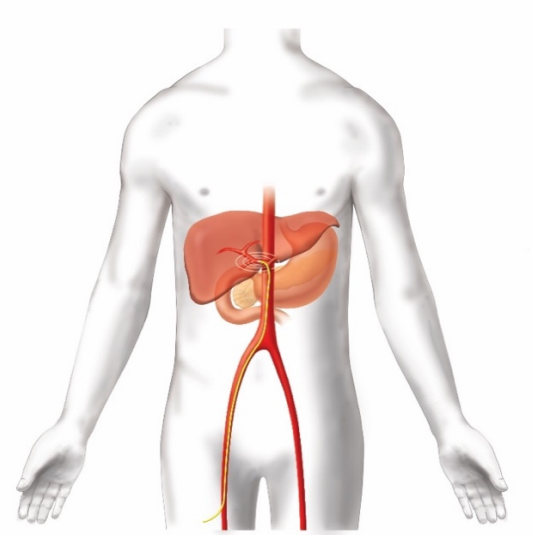
## Importance of the liver nerves in type 2 diabetes

Previous research has shown that disrupting the nerves in the hepatic artery may return the liver to a more normal state and may increase the amount of blood sugar the liver takes up during hyperglycemia. As a result, diabetes may be better controlled after having this procedure.

## The Metabolic Neuromodulation Therapy Procedure

Patients will be admitted to the ward on the morning of the procedure and transferred to the cardiac catheter suite for the procedure. They will be given a sedative, and the right groin will be injected with a local anesthetic before passing the catheter into the right femoral artery in the groin. This catheter will pass through the femoral artery into the liver artery, which will be treated with radiofrequency energy. Up to 8 treatments will be performed, each of which takes about 2 minutes. The entire procedure, including time in the cardiac catheter suite, will take approximately one hour. There may be some pain, but this is

likely only to last a short time and will be controlled with pain medication as necessary. At the end of the procedure, the groin will be sealed with an angioseal. The patients will be in bed for at least 4 hours after the procedure, and will stay in hospital overnight. In the morning, before discharge, a brief physical exam (weight, blood pressure, and heart rate) will be performed. A fasting blood sample will be collected and analyzed.



*Procedure and anatomy schematic*

**Post procedure side effects**

There may be some discomfort in the abdomen. If this is the case, the patient will be given medication to reduce this

discomfort. There may be oozing, bruising, or a small haematoma (lump) at the groin artery puncture site. This will be covered with a small dressing. The main risks of the procedure are believed to be similar to the risks of other common procedures requiring catheterisation of the arteries. Possible risks of the catheterisation procedure include injury to the hepatic artery, kidney damage, clotting in the arteries, or bleeding. There are additional risks that could possibly be associated with the Metabolic Neuromodulation Therapy procedure or response to treatment. There may be side effects that the researchers do not expect or do not know about and that may be serious.

Metabolic Neuromodulation Therapy is performed in a research study, the COMPLEMENT Study. More information can be found in the Participant Information Sheet and Consent Form, and through discussions with the study team.

**Who May Participate**

- Age 18 to 70 years
- Type 2 diabetes
- HbA1c 7.5–10% (58-86 mmol/mol)
- Stable lifestyle modifications
- Metformin ≥ 1500 mg/day
- BMI ≤ 45 kg/$m^2$

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## Toll free number for patients 0800 004626

The Metabolic Neuromodulation System is not currently approved in New Zealand and is limited to investigational use only for the COMPLEMENT study
CAUTION: INVESTIGATIONAL DEVICE, LIMITED TO INVESTIGATIONAL USE