



# Implanting a baroreceptor stimulation device for resistant hypertension

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www.nice.org.uk

## What has NICE said?

There is not enough evidence to be sure about how well this procedure works or how safe it is. For this reason, it should only be done as part of a research study.

NICE may look at the procedure again if more evidence is published.

#### What does this mean for me?

Your health professional can only offer you this procedure as part of a research study. Details of your procedure will be collected.

## The condition

Hypertension (high blood pressure) increases the risk of having a heart attack, stroke or

chronic kidney disease. Resistant hypertension is high blood pressure that is difficult to control, remaining higher than 140/90 mmHg despite drug treatment.

Treatment for hypertension includes lifestyle changes such as diet and exercise. Drug treatment is usually offered if the person's blood pressure remains high.

NICE has looked at <u>implanting a baroreceptor simulation device</u> as another treatment option when drug treatment does not control blood pressure well enough.

NHS Choices (<u>www.nhs.uk</u>) and NICE's information for the public about <u>hypertension</u> may be a good place to find out more.

# The procedure

The procedure is usually done with the patient under general anaesthesia or sedation.

A small battery-powered device is implanted under the skin of the collarbone. It is connected by a thin wire to an electrode, which is attached to part of an artery in the neck (a carotid sinus). This area contains baroreceptors, which are sensitive to changes in blood pressure. When stimulated by electrical impulses from the device, the baroreceptors help the body to lower blood pressure. An earlier version of the device used 2 electrodes.

The device is tested to check that it's in the correct place and working properly. It is usually activated by clinic staff about a month after it has been implanted. At follow-up appointments in hospital the clinic staff can change the settings or turn the device off if necessary.

# Benefits and risks

When NICE looked at the evidence, it decided that there was not enough evidence about this procedure. NICE looked at 5 studies (377 patients) that used the device with 2 electrodes and 3 studies (99 patients) that used the device with 1 electrode.

Generally, the studies showed the following benefits for up to 28 months after implanting the device:

reduced blood pressure in some patients (using the device with 1 or 2 electrodes)

• fewer drugs were needed to control blood pressure in patients whose blood pressure responded to the device with 2 electrodes.

The studies showed that the risks of the procedure for the device with 2 electrodes were:

- nerve damage, which was permanent in 14 patients and temporary in 12 patients
- stroke related to high blood pressure in 6 patients. Another patient had a stroke around the time of the operation, with no lasting effects
- a sudden, severe increase in blood pressure in 16 patients
- infection needing removal of the device in 4 patients
- wound problems in 7 patients
- breathing complications after the device was implanted in 7 patients
- movement of the device in 1 patient, needing surgery to reposition it.

The studies showed that the risks of the procedure for the device with 1 electrode were:

- blood collecting at the site where the device was implanted in 1 patient
- pain within 30 days of the device being implanted in 1 patient, which cleared up by itself.

If you want to know more about the studies, see the <u>guidance</u>. Ask your health professional to explain anything you don't understand.

# Questions to ask your health professional

- What does the procedure involve?
- What are the benefits I might get?
- How good are my chances of getting those benefits? Could having the procedure make me feel worse?
- Are there alternative procedures?
- What are the risks of the procedure?

- Are the risks minor or serious? How likely are they to happen?
- What care will I need after the procedure?
- What happens if something goes wrong?
- What may happen if I don't have the procedure?

# Medical terms explained

#### 140/90 mmHg

Blood pressure is made up of 2 measurements, one taken when your heart is beating and pumping blood (known as systolic blood pressure) and another taken when your heart is filling up with blood between beats (known as diastolic blood pressure). It is measured in millimetres of mercury (which is written as mmHg) and is recorded as systolic blood pressure over diastolic blood pressure, for example 140/90 mmHg.

# About this information

NICE <u>interventional procedures guidance</u> advises the NHS on the safety of a procedure and how well it works.

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## Accreditation

