NICE guidance

Transcutaneous electrical stimulation of the trigeminal nerve for ADHD

Interventional procedures guidance
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www.nice.org.uk/guidance/ipg748

Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful

discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

1 Recommendations

1.1 Evidence on the safety and efficacy of transcutaneous electrical stimulation of the trigeminal nerve for attention deficit hyperactivity disorder (ADHD) is inadequate in quality and quantity. Therefore, this procedure should only be used in the context of research. Find out what only in research means on the NICE interventional procedures guidance page.

1.2 Further research could be in the form of multicentre, sham-controlled (or other suitable comparator) trials and should include details of patient selection, treatment protocols, adherence and long-term outcomes.

2 The condition, current treatments and procedure

The condition

2.1 Attention deficit hyperactivity disorder (ADHD) is a heterogeneous disorder characterised by the core symptoms of hyperactivity, impulsivity and inattention, which are judged excessive for the person's age or level of overall development. Symptoms are usually evident in childhood and may persist into adulthood.

Current treatments

2.2 Treatment for ADHD may be non-pharmacological, pharmacological or a combination of both. Non-pharmacological treatment includes cognitive behavioural therapy and parent-training programmes (for parents of children and young people with ADHD). Pharmacological treatment includes central nervous system stimulants such as methylphenidate and amphetamines, and non-stimulants such as atomoxetine.

The procedure

2.3 In this procedure, an external trigeminal nerve stimulation device is worn on the clothes and attached by wires to a single-use adhesive patch which is worn overnight. The patch contains 2 electrodes placed over the left and right V1 branches of the trigeminal nerve on the forehead. The stimulator bilaterally stimulates the trigeminal nerve for approximately 8 hours. For children, parents or carers attach the device. In a typical treatment course, stimulation is given nightly for approximately 4 weeks. Treatment duration may vary; a clinical response may take longer, and continued therapy may be needed.

2.4 The mechanism of action is not completely understood. The trigeminal nerve connects to regions of the brain that may be associated with selective maintenance of attention and arousal, and it is thought that its stimulation improves the symptoms of ADHD.

3 Committee considerations

The evidence

3.1 NICE did a rapid review of the published literature on the efficacy and safety of this procedure. This comprised a comprehensive literature search and detailed review of the evidence from 3 sources, which was discussed by the committee. The evidence included 1 randomised controlled trial (with 1 secondary analysis) and 1 open-label trial. It is presented in the summary of key evidence section in the interventional

procedures overview.

3.2 The professional experts and the committee considered the key efficacy outcomes to be: improved quality of life, reduced symptoms and reduced need for medication.

3.3 The professional experts and the committee considered the key safety outcomes to be: pain, skin irritation, negative effect on cognitive function and worsening of symptoms.

3.4 Patient commentary was sought but none was received.

Committee comments

3.5 The committee was informed that the procedure is primarily indicated for people for whom medication is unsuitable.

3.6 The device has regulatory approval for use in people aged 7 and over, but all the evidence that the committee considered was from children.

3.7 The committee was informed that treatment usually takes place at night and that a course of treatment may need to be repeated.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.