Clonidine for treating attention deficit hyperactivity disorder (ADHD) in children and young people

Information for the public
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About this information

This information explains the evidence summary about the off-label use of clonidine to treat attention deficit hyperactivity disorder (ADHD) in children and young people (under the age of 18 years). The evidence summary is an overview of the available information about this medicine. It aims to help prescribers and patients when they are considering whether or not to use an unlicensed or off-label treatment. The summary does not contain recommendations from NICE on whether the medicine should be used.

Licensing medicines

In the UK, medicines need to have a licence before they can be marketed. To get a licence, the manufacturer of the medicine has to provide evidence that shows that the medicine works well enough and is safe enough to be used for a specific condition and for a specific group of patients, and that they can manufacture the medicine to the required quality. Medicines can be prescribed without a licence (an 'unlicensed medicine') if there is no suitable licensed alternative and it is likely to benefit the patient.

A medicine can also be prescribed 'off-label'. This means the prescriber wants to use it in a different way than is set out in the terms of its licence. This could mean using the medicine for a different condition or a different group of patients, or it could mean a change in the dose or that the medicine is taken in a different way. There is more information about licensing medicines on NHS Choices.
What is ADHD?

Attention deficit hyperactivity disorder (ADHD) is one of the most common behavioural disorders in children and young people. Symptoms of ADHD can include being:

- inattentive – unable to concentrate for very long or finish a task, disorganised, often losing things, easily distracted and forgetful, unable to listen when people are talking
- hyperactive – fidgety and unable to sit still, restless (children may be running or climbing much of the time), talking constantly, noisy, having difficulty doing quiet activities
- impulsive – speaking without thinking about the consequences, interrupting other people, unable to wait or take their turn.

Many children who have ADHD also have other conditions. The most common are those affecting mood, conduct or learning as well as anxiety disorders. ADHD is also common in children diagnosed with Tourette's syndrome and other chronic tic disorders. Tics are sudden twitches, movements or sounds that people do repeatedly and cannot control or stop.

The exact cause of ADHD is not fully understood but research shows that the brain works differently in people with ADHD compared with people who do not have the condition. This may be due to the wrong levels of certain chemicals in the brain, or certain chemicals not working properly.

About clonidine

Clonidine is a drug that stimulates certain parts of the brain that are involved in regulating the heart and blood vessel system. The exact way that clonidine may help improve ADHD symptoms is not clear. However, clonidine is thought to act on an area of the brain that regulates attention and impulse control.

Clonidine is available in different strengths, ranging from a 25 microgram tablet up to a 200 microgram tablet (a higher number means there is more clonidine in the tablet, and so the medicine is stronger).

The 25 microgram clonidine tablet is licensed in the UK to prevent migraine in adults, and to prevent hot flushes associated with the menopause in women. A stronger 100 microgram tablet (which is sold under the brand name Catapres) is also licensed in the UK to treat high blood pressure (also known as hypertension) in adults. Neither of these is licensed in the UK to treat
ADHD. Therefore, using these clonidine tablets to treat ADHD in a person of any age in the UK is described as off-label.

Clonidine is also available as 'slow-release' tablets. These don't have a licence in the UK to treat any type of condition and so use of these is described as unlicensed.

There are ways to treat ADHD that don't include using drugs, such as training programmes or therapy, and these are normally tried first. If these haven't worked or the ADHD symptoms are very bad, there are 3 drugs that are licensed in the UK to treat ADHD which may be tried; these are called methylphenidate and dexamfetamine (which are known as psychostimulants or sometimes just 'stimulants'), and atomoxetine.

If none of these drugs is suitable, or they don't work for the child or young person, then other drugs that don't have a license for ADHD are sometimes tried, such as clonidine.

**Summary of possible benefits and harms**

**How well does clonidine work?**

Three studies were found that looked at how well clonidine worked in children and young people with ADHD. In 2 of these studies, the child or young person had another condition as well as ADHD.

Two of the studies looked at how well clonidine worked in a total of 258 children and young people aged 7 to 12 or 14 years with ADHD. One study included children and young people who had either Tourette's syndrome or another chronic tic disorder as well as ADHD (136 children and young people), the other did not (122 children and young people with ADHD only). All children and young people were given 1 of the following treatments for 16 weeks: clonidine, a stimulant, a placebo or dummy tablet (a tablet that doesn't contain any active ingredient), or clonidine and a stimulant together. The study in children with ADHD only, found that clonidine, when taken at the same time as a stimulant, didn't work any better than a stimulant on its own at improving symptoms of ADHD. There also wasn't any difference between all 4 treatments in improving quality of life for children and young people. However, compared with taking no treatment, taking clonidine and a stimulant at the same time improved ADHD symptoms in the study of children and young people who also had either Tourette's or a chronic tic disorder.

The third study looked at how well clonidine worked in 67 children and young people aged 6 to 14 years with ADHD who also had either conduct disorder (a pattern of defiant or impulsive behaviour) or oppositional defiant disorder (a pattern of disobedient behaviour towards authority
figures). In addition to stimulants they were already taking, the children and young people were given either clonidine syrup or a dummy syrup (with no active ingredient) for 6 weeks. The study had mixed results. It found that clonidine was no better than the dummy treatment at improving hyperactivity symptoms (see What is ADHD?). However, more children and young people who were taking clonidine had improved conduct disorder symptoms (antisocial, aggressive or defiant behaviour) than those taking the dummy treatment.

**What are the possible harms or side effects?**

In the 2 studies where children and young people were given clonidine, a stimulant medicine, a dummy tablet, or clonidine and a stimulant together, taking clonidine at the same time as a stimulant caused more side effects than when the stimulant was taken on its own. However, in most children and young people the side effects were not bad enough for them to stop taking the medicine or to drop out of the study. The main side effects that children or young people had when taking clonidine were feeling drowsy and sedated. The studies suggested this may be a temporary side effect that lessens over time, but this is not certain.

One study, which included 122 children and young people aged 7 to 12 years, found that those who were using clonidine, either taken on its own or with a stimulant, were more likely to develop a slow heart rate (less than 60 beats per minute) than those who were only taking a stimulant or who hadn't received any treatment in the study (they were given a dummy treatment). One child who was taking clonidine and a stimulant withdrew from the study after 14 weeks because of a suspected heart problem.

Because the studies were quite small and only lasted a short time, additional serious side effects from clonidine cannot be ruled out. Children and young people with serious heart problems were not allowed to take part in the studies and so the risks of side effects of the drug on this group are not known, but may be higher.

Please note that the results of the research studies only indicate the benefits and harms for the population in the studies. It is not possible to predict what the benefits and harms will be for an individual child or young person being treated with clonidine.

**Prescribing clonidine**

If a prescriber wants to use an unlicensed or off-label medicine, they must follow their professional guide, for example for doctors the General Medical Council's good practice guidelines. These include giving information about the treatment and discussing the possible benefits and harms so
that the patient has enough information to decide whether or not to have the treatment. This is called giving informed consent.

A full version of the summary aimed at healthcare professionals is available on the NICE website. The summary for healthcare professionals does not contain recommendations from NICE on whether the medicine should be used.

If your doctor is suggesting that you (or, if you are reading this as a parent or carer: your child) might try clonidine for ADHD, you might like to ask some of the questions below.

Questions to ask

- Why am I (or my child) being offered an unlicensed or off-label medicine?
- What does the treatment involve?
- What are the benefits I (they) might get?
- How good are my (their) chances of getting those benefits?
- Could having the treatment make me (them) feel worse?
- Are there alternative treatments?
- What are the risks of the treatment?
- Are the risks minor or serious? How likely are they to happen?
- What may happen if I (they) don't have the treatment?

More information

The evidence summary and this information for the public were produced for NICE by Bazian Ltd.

NICE has published information about how evidence summaries for unlicensed and off-label medicines are developed.

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