Tranexamic acid following trauma

Information for the public
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About this information

This information explains the evidence summary about the off-label use of tranexamic acid for significant haemorrhage (severe bleeding) following trauma. 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 significant haemorrhage following trauma?

Significant haemorrhage following trauma is where a large volume of blood is lost due to a major injury (‘trauma’). Serious bleeding is one of the main reasons why people die after severe injury.

About tranexamic acid

Tranexamic acid is a drug used to stop or reduce unwanted bleeding. It does this by stopping blood clots from breaking down, allowing the clots to form and stop the bleeding.

Tranexamic acid has been given a licence in Europe and the UK for use in certain conditions, for example after surgery, or in women with heavy bleeding during their periods. However, it does not have a licence for use after trauma, so use in this way is described as 'off-label'.

When tranexamic acid is used to prevent or stop bleeding after severe injury, it is slowly injected into a vein over about 8 hours (this is called a slow intravenous injection).

Summary of possible benefits and harms

The effects of tranexamic acid were assessed in a research study involving over 20,000 patients with severe injury (trauma) who had (or were at risk of) severe bleeding. People were given either tranexamic acid or placebo (dummy treatment). A greater percentage of people given tranexamic acid survived their injuries compared with people given placebo. People who were given tranexamic acid were no more likely to experience side effects of treatment than those given placebo.

There is some evidence from the study that tranexamic acid works best if given within 3 hours of the injury. There are alternative treatments which can be given to help stop bleeding, such as transfusions of blood or individual components of blood.

How well does tranexamic acid work?

In the research study, giving tranexamic acid to patients with, or at risk of, severe bleeding resulted in fewer patients dying from any cause, including dying from bleeding.

In the study, for every 1000 people who were given placebo, 160 died within 4 weeks of their injury. However, for every 1000 people in the study who were given tranexamic acid, only 145 people died
within 4 weeks of their injury. In other words, on average, an extra 15 people in every 1000 survived because they were given tranexamic acid.

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

In the research study, people who were given tranexamic acid were no more likely to experience side effects of treatment than those given placebo. This included the risk of problems related to blood clotting (including heart attacks, stroke or clots in the lungs).

Please note that the results of the research study only indicate the benefits and harms for the population in the study. It is not possible to predict what the benefits and harms will be for an individual patient being treated with tranexamic acid.

**Prescribing tranexamic acid**

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.

But in an emergency, healthcare professionals may need to give treatment straightaway, without getting informed consent, when it is in someone's best interests. This is likely to be the case in many situations where tranexamic acid would be used to prevent, reduce or stop serious bleeding.

The full version of the summary aimed at healthcare professionals is available at http://publications.nice.org.uk/esuom1-significant-haemorrhage-following-trauma-tranexamic-acid-esuom1. The summary for healthcare professionals does not contain recommendations from NICE on whether the medicine should be used.

**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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