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EMA reviewing use of omega-3 fatty acid medicines after heart attacks

Recent data indicate these medicines may not prevent recurrence of heart disease or stroke

The European Medicines Agency (EMA) is reviewing the use of omega-3 fatty acid medicines in patients who have had a heart attack, following research showing that these oral products may not prevent recurrence of heart disease or stroke.

A recent analysis of 10 studies in around 78,000 patients found that adding omega 3-fatty acid medicines to standard treatment did not significantly reduce heart attacks, stroke or other heart and circulatory problems.[1] These findings were similar to those from other studies published in 2012, which also found no significant reduction in heart disease.[2-4]

Omega-3 fatty acid medicines are used in most EU countries to prevent heart disease and stroke after a heart attack, in combination with other medicines. They are also used to reduce levels of certain types of blood fat. At the time of their approval, available data showed some benefits in reducing heart attacks, stroke and deaths although the benefits were considered small.

At the request of the Swedish medicines agency, EMA will now review data on the benefits and risks of these medicines, including the most recent analyses, and make a recommendation concerning their authorisations in the EU.

The review will be conducted by EMA's Committee for Medicinal Products for Human Use (CHMP).

More about the medicines

Omega 3-fatty acid medicines are oral products containing the fatty acids eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) commonly found in fish oils. They are authorised in most EU countries for preventing heart disease or stroke after a heart attack (in combination with other medicines) and for reducing certain types of blood fats. This review is focused on the medicines' use in patients who have had a heart attack.

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More about the procedure

The review of omega-3 fatty acid medicines was initiated on 22 March 2018 at the request of the Swedish medicines agency under Article 31 of Directive 2001/83/EC.

The review will be carried out by the Committee for Medicinal Products for Human Use (CHMP), responsible for questions concerning medicines for human use. The CHMP opinion will then be forwarded to the European Commission, which will issue a final legally binding decision applicable in all EU Member States.

References

1. Aung T, Halsey J, Kromhout D, et al. Associations of omega-3 fatty acid supplement use with cardiovascular disease Risks: meta-analysis of 10 trials involving 77917 individuals. JAMA Cardiol 2018. doi:10.1001/jamacardio.2017.5205

2. Kotwal S, Jun M, Sullivan D, Perkovic V, Neal B. Omega 3 Fatty acids and cardiovascular outcomes: systematic review and meta-analysis. Circ Cardiovasc Qual Outcomes 2012;5:808-18.

3. Kwak SM, Myung SK, Lee YJ, Seo HG, Korean Meta-analysis Study G. Efficacy of omega-3 fatty acid supplements (eicosapentaenoic acid and docosahexaenoic acid) in the secondary prevention of cardiovascular disease: a meta-analysis of randomized, double-blind, placebo-controlled trials. Arch Intern Med 2012;172:686-94.

4. Rizos EC, Ntzani EE, Bika E, Kostapanos MS, Elisaf MS. Association between omega-3 fatty acid supplementation and risk of major cardiovascular disease events: a systematic review and meta-analysis. JAMA 2012;308:1024-33.