



November 2007

NEWS BRIEFS from the Aspirin Foundation

ARRIVE - one of the largest ever trials of aspirin to prevent first heart attack and stroke

Aspirin is now being tested in one of the largest clinical trials of its kind ever conducted. The **Aspirin to Reduce Risk of Initial Vascular Events (ARRIVE)** trial, announced at the European Society of Cardiology Congress in Vienna in September, will show whether low-dose aspirin can reduce the risk of first heart attacks and stroke in people who are at moderate risk.

We already know that low-dose aspirin reduces these risks for people who have suffered such an event, and for people who have not had a heart attack or stroke but who are nonetheless at high risk of doing so. ARRIVE, sponsored by Bayer HealthCare, will expand the already existing and strong body of evidence on the effectiveness and safety of aspirin in the many people who have a lower but still significant level of risk.

ARRIVE: a summary

ARRIVE, a multinational trial, will recruit about 12,000 patients in 400 centres in Germany, Italy, Spain, the UK and the US. It is expected to take about 5 years to accumulate enough data for a statistically reliable analysis of the effect of low-dose aspirin on the incidence of fatal and non-fatal heart attacks and strokes in this moderate risk population. The first patient was recruited to the trial on July 18th this year. The results should be available in 2013.

Why do we need ARRIVE?

Low-dose aspirin is recommended (subject to contraindications) for everyone who has had a heart attack or stroke because it reduces their risk of experiencing a similar event by about 30 per cent.¹ This is called *secondary prevention* and the role of low-dose aspirin is well established.

In addition, physicians are also recommended to consider treatment with low-dose aspirin by many evidence-based clinical practice guidelines, such as those

issued by the European Society of Cardiology, among others, for patients determined to be at moderate risk. This is generally defined as older people (age over 50) who have not yet had a cardiovascular event but may be at increased risk of doing so because they have several risk factors such as hypertension and high cholesterol, or are classified as high-risk due to a long-term condition such as diabetes. This is called *primary prevention*. An analysis of six primary prevention trials involving over 90,000 people at increased risk but with no known cardiovascular disease has shown that low-dose aspirin reduced the risk of fatal and non-fatal first heart attack by 23 per cent; it also reduced the risk of death but this was not statistically significant.²

While aspirin is already approved for primary prevention in 36 countries around the world, there is still a great opportunity to bring the benefits of aspirin to a larger number of appropriate moderate risk patients. ARRIVE will further enrich existing information about the balance of its benefits and risks for people whose risk of a cardiovascular event in the next ten years is 20 - 30 per cent - that is, men aged at least 50 who have two or three risk factors for cardiovascular events (such as cigarette smoking, a family history of heart disease, hypertension or high cholesterol) and women aged at least 60 who have three or more risk factors.

A new risk assessment tool for ARRIVE

An individual's cardiovascular risk is estimated using a tool developed by observing the pattern of cardiovascular events in different populations. Potential participants in ARRIVE will each be enrolled on the basis of inclusion/exclusion criteria determined using a new method based on four of the risk assessment tools in current use; this will provide risk estimates that allow for differences between countries with high- and low-risk populations. Bayer is working to refine the methodology so the new tool can be used in routine clinical practice by practitioners worldwide.

Summary

Low-dose aspirin is already established as the treatment of choice for secondary prevention of cardiovascular events. ARRIVE, one of the most ambitious clinical trials of aspirin ever undertaken, will further expand the current body of evidence supporting the use of aspirin for primary prevention in people at moderate risk of cardiovascular events. When it is completed, we will have an even clearer view of the role of low-dose aspirin.

References

1. Aspirin Foundation. Aspirin in secondary prevention. July 2006 (www.aspirin-foundation.com/suitability/documents/Aspirininsecondaryprevention.pdf; accessed 17.10.07)
2. Bartolucci A, Howard G. Meta-analysis of data from the six primary prevention trials of cardiovascular events using acetylsalicylic acid. *Am J Cardiol* 2006;98:746-50