National Institute on Aging

Announcement

NIA Ends Intervention Phase of ASPREE Trial Early

The National Institute on Aging (NIA), part of the National Institutes of Health (NIH), today announced that it is ending the intervention phase of the ASPirin in Reducing Events in the Elderly (ASPREE) trial, effective immediately. Study participants have been notified and instructed to stop taking the study medication: 100 mg of aspirin or placebo. The intervention phase was originally planned to finish in December 2017.

The main aim of the study is to find out whether daily low dose aspirin would extend life free of disability and dementia in healthy older people. On reviewing the most recent data, NIA has seen very little difference between the groups taking aspirin or placebo in length of life free of dementia and disability since the start of the study treatment. The NIA has now concluded that it is extremely unlikely that the study would show a benefit for this, the main study outcome, even if participants continued to take study medication through December 2017 as originally planned.

Participants will continue to be monitored and researchers will further analyze the data collected. This will provide additional information about the effects of low-dose aspirin on specific conditions as people age, such as cancer, cardiovascular disease, stroke, depression, bleeding and cognitive impairment.

Full data collection for this phase of the study will be completed in late 2017. An analysis of these data is expected to be completed and submitted for publication in early 2018.

ASPREE is an international randomized, double-blind, placebo controlled trial in 19,114 older people (16,703 in Australia and 2,411 in the United States). The study started in 2010 and enrolled participants aged 70 years and above, except for Hispanic and African American groups in the U.S., for whom the minimum age of entry was 65 years.

Participants in ASPREE were free of medical conditions requiring aspirin use at study enrollment. The results of ASPREE will not apply to those with a proven indication for aspirin, such as those with cardiovascular disease or a previous stroke. In addition, ASPREE results do not address aspirin's effects in younger people.

The ASPREE study was funded primarily by the National Institute on Aging and the National Cancer Institute of the NIH. The Australian component of the study also received substantial

funding from the Australian National Health and Medical Research Council and Monash University. Aspirin and placebo were supplied by Bayer, which has had no other involvement with the study.

The U.S component of the study is led by Anne Murray, M.D., M.S., of the Berman Center for Outcomes & Clinical Research and the Minneapolis Medical Research Foundation at Hennepin County Medical Center. The Australian component of the study is led by Professor John McNeil, MBBS, Ph.D., FRACP, of Monash University in Melbourne.

The study is supported through NIH award U01AG029824. Clinical trial number NCT 01038583. More information is available at www.aspree.org.

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