ASPREE

U.S. PRINCIPAL INVESTIGATOR UPDATE ON LARGEST PRIMARY PREVENTION ASPIRIN STUDY IN ELDERLY

Summer 2017

About ASPREE:

ASPirin in **R**educing **E**vents in the **E**lderly

U.S. Participants
Total enrolled: 2,411

ASPREE Overview:

- A double-blind, randomized, placebo controlled clinical trial of 100 mg enteric-coated aspirin for primary prevention in Caucasians aged 70 and older, and minorities aged 65 and older
- In June 2017, transitioned from on study medication to off study medication
- Has 33 sites in the U.S.
- 15 sub-studies in Australia and 1 sub-study in the U.S.
- Expected publication of primary paper is early 2018
- ACES sub-study has received 1174 blood, 1203 urine, 99 saliva, and 51 tumor samples

When will I find out what medication I was on? New!

We will be providing information about which study drug you were taking shortly after the main paper is published in 2018.

Anne Murray, MD, MSc
Professor of Medicine and Geriatrics
U.S. ASPREE Principal Investigator
Medical Director
The Berman Center for Clinical Research
Hennepin County Medical Center

First, we want to thank you for your dedication in taking the ASPREE journey together with us thus far. You are contributing to the largest aspirin trial ever conducted across two countries in healthy older people.

With everything we have already collected, why do we need your continued participation in ASPREE XT?

We have the unique **one time** opportunity to see if there are any long-lasting or delayed effects of being on low dose daily aspirin for about 4 and a half years in a very large, healthy older group of Americans and Australians.

Delayed effects of aspirin could occur because aspirin not only decreases the risk of blood clots and strokes, but also reduces inflammation. As **inflammation** can cause gradual damage that contribute to cancer, arthritis, depression, and brain changes seen in memory loss, we want to see if *slowing down inflammation* for several years might result in less decline or even improvement in some of these outcomes. In a sense, we want to see if aspirin might 'reset' the clock for some of these diseases. Delayed or prolonged effects of other medications have been observed in previous clinical trials. This is especially true for cancer, where it has been shown that it takes several years to see a beneficial effect of aspirin (even after it is discontinued) in preventing colon cancer or other cancers. **This is why it is so important that we continue to collect cancer tissue specimens and medical history in ASPREE XT**.

We will also see whether there is a delayed effect of aspirin on such diseases as **knee arthritis**, **depression**, **or memory loss**. In addition, because aspirin can also cause harm by increasing the risk of bleeding and anemia (low red blood cells), we will be measuring the extent that there is less bleeding or anemia now that medication has been stopped. Also, remember that since the ASPREE data will not be analyzed fully until early 2018, we do not know yet whether positive or negative effects of aspirin were seen for many outcomes. **So far**, **we only know that there was no net effect of aspirin versus placebo on preventing the primary combined outcome of dementia**, **physical disability**, **or death**. Once the data is analyzed, we can determine if the effects of aspirin on other outcomes go away after aspirin is discontinued, or persist.

U.S. PRINCIPAL INVESTIGATOR UPDATE ON LARGEST PRIMARY PREVENTION ASPIRIN STUDY IN ELDERLY (continued)

Since study participants are no longer on study medication, what new information will be learned by additional data collection?

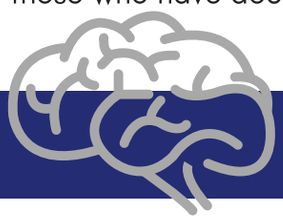
We plan to collect information that is very similar to what was previously collected during your ASPREE visit such as cognitive and physical function testing (gait and grip strength), blood tests, questions about your health, including cancer and cancer tissue. We will use your information to learn about aspirin's long-term effects.

What is ASPREE XT, and what is my role in ASPREE XT?

ASPREE XT is an extension of the original ASPREE study, but off medication. We plan to continue face- to face visits, phone calls, and tumor tissue collection. More information will be shared with your study site and you yet this year. It is unclear how frequent the follow up visits will be until we know how much funding will be available from the National Institutes of Health (both the National Institute on Aging and National Cancer Institute), but we hope to continue ASPREE XT for an additional 5 years.

What if I am not as healthy as I was when I started in ASPREE? Can I still participate if I am not well?

It is important that everyone who is willing to continue to participate: especially those with increased medical problems, in whom aspirin may potentially have a delayed effect. Without broad continued participation we won't get a true picture of the long- lasting effects of aspirin in *all groups* of surviving participants, healthy or not, and our results would be unbalanced, or 'biased'. We can always tailor visits for those who have decreased endurance or disabilities.



BRAIN GAMES

	5							4
1		9				5		
		4	9				7	
2		1	8	5		4		3
3								8
8		5		6	4	9		1
	6				1	2		
		8				6		7
5							1	

5				9		2		4
		8	7					9
				5		6	8	
		5			7			2
9	7						6	8
2			6			5		
	4	6		7				
7					4	8		
8		3		1				5

Sudoku puzzles are provided by www.sudokuoftheday.com – visit them and get a new Sudoku every day!

SITE SPOTLIGHT
PENNINGTON BIOMEDICAL RESEARCH CENTER (BATON ROUGE, LA)

(Pictured from left to right): Frank Greenway, MD, Brandy Starns, MS, Daniel Hsia, MD, Aimee Stewart, Robert Brouillette, Aubrey Windham, Jeffrey Keller, PhD, Ron Monce, PA.

Pennington Biomedical is a campus of Louisiana State University and has a mission to discover the triggers of chronic diseases through innovative research that improves human health across the lifespan. For nearly 30 years we have conducted translational research with basic, clinical, and population scientists all under one roof.

We are home to 4 NIH-funded centers as well as the Institute for Dementia Research and Prevention (IDRP), an Alzheimer's Disease Cooperative Study Site, led by Jeffrey Keller, PhD, a Co-I on the ASPREE study. The IDRP has performed cognitive testing procedures and has contributed their expertise to the study. In addition, we have participated in a number of longstanding prevention and treatment trials such as the Diabetes Prevention Program and the LookAHEAD study.

The original site PI for the ASPREE Study was Timothy Church, MD, MPH, PhD who led the study until his departure in 2013. The study was transitioned to Daniel Hsia, MD, an Assistant Professor in the Clinical Trials Unit. He is currently involved in a number of multi-centered clinical trials involving both adults and children. His interests include finding new treatments and screening tools for obesity, diabetes and their complications across all ages. Frank Greenway, MD and Ron Monce, PA also serve as Co-Is and have helped to support the study. Brandy Starns, MS has been the lead coordinator since 2016 and oversees the scheduling and completion of study visits. Lauren Harrington, RN and Aubrey Windham serve as backup coordinators and support Brandy's efforts.

We are indebted to all of the study participants who have volunteered their time and have contributed so much to the ASPREE study. We have had the privilege to follow these individuals and form relationships over time as we look to improve the health of all people throughout the lifespan.

ASPREE

ASPREE TRANSITION UPDATE
BERMAN CENTER FOR CLINICAL RESEARCH (MINNEAPOLIS, MN)

(Pictured left to right): Barb Wicklund, Molly Prozinski, Rachel Tappe, Ashley Farnum, Ellie Wolinkski, Nate Tessum, and Ashley Johnson

A HUGE thank you to participants for returning your study medication and Health Questionnaires!

Continue to contact your local ASPREE site if you have any questions about the ASPREE study, transition, or ASPREE XT.