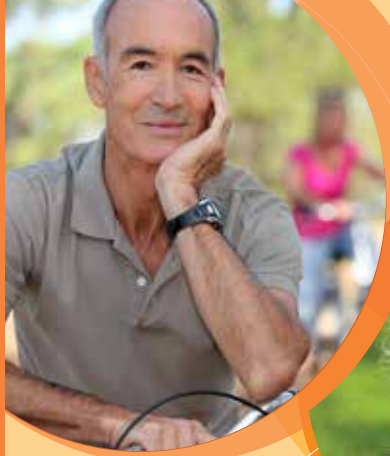
patient
study guide



A Study for People with Mild-to-Moderate Alzheimer's Disease

GRIFOLS

alzheimer management by albumin replacement

ambar

Welcome to the AMBAR study!

Thank you for taking part in the AMBAR (Alzheimer Management By Albumin Replacement) study. AMBAR is a clinical research study that looks at using an experimental plasma exchange as a possible future procedure for Alzheimer's disease and how it impacts cognition and daily functioning among study participants. The AMBAR study will use plasma exchange to separate and remove plasma from the blood and replace the plasma with albumin.

This Study Guide gives you information on what you need to do to participate in AMBAR. There is space at the end to write down your appointments and questions. Whether you are a person with Alzheimer's disease or a caregiver (or family member), this Guide is for *your* use, so please keep it for reference throughout the time you are in the AMBAR study. You should always refer to the study informed consent for a complete list of study activities.

Remember, it is always your choice to be in AMBAR. If you sign up and later decide you do not want to continue, you may stop at any time. Simply tell your study doctor. He or she will schedule your final study visit.

Thank you for taking part in the AMBAR study! By participating in the study, you and your caregiver (or family member) will help us collect information that may help others with Alzheimer's disease.

Sincerely,

The AMBAR Study Team

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About AMBAR

AMBAR is a clinical research study that looks at using an experimental plasma exchange as a possible future procedure for Alzheimer's disease. The AMBAR study will use plasma exchange to separate and remove plasma from the blood and replace it with albumin.

The study will look at the safety of using albumin, the investigational procedure, in patients with mild-to-moderate Alzheimer's disease to see how it impacts cognition and daily functioning among study participants.

The study will include 364 patients at centers in Spain and the United States.

AMBAR Participation

After signing the Informed Consent Form (ICF), you will be enrolled in AMBAR and will:

- ✓ Go through a 3 week screening period
- ✓ Be assigned to either*:
  - one of 3 study treatment groups; or
  - a control group
- ✓ Receive 1 Full plasma exchange per week for 6 weeks (6 FPEs), followed by 12 Low Volume Plasma Exchange (12 LVPEs)

While enrolled in AMBAR, you will receive study-related exams and procedures at no cost to you.

**You will be blinded to the group to which you are assigned. This means, you will NOT know if you are part of the control group or one of the study treatment groups.*

The Control Group

Clinical research studies test the safety and effectiveness of investigational medications or procedures. To do this, many clinical studies, like AMBAR, include a control group. People who are part of the control group will not receive medication or treatment. Researchers then compare the control group against participants receiving the medication or procedures.

The control group is very important. It allows researchers to see if the investigational medication or procedure is really working. By participating in research as the control group, you may help make a difference for others with Alzheimer's disease.

There is no cure for Alzheimer's disease. Research is being done to better understand the disease and to advance options for its future prevention and therapy.

The Study Treatment Group

For AMBAR, there are 3 study treatment groups in which patients will receive albumin, the investigational drug being tested. The main difference between the 3 groups is the amount & concentration of the albumin being given to participants. Below are the 3 study treatment groups for AMBAR:

- Study Treatment Group 1: Each patient will receive 12 plasma exchanges: 9 with albumin and 3 with intravenous immunoglobulin (IVIG).
- Study Treatment Group 2: Each patient will receive 12 plasma exchanges. 9 with albumin and 3 with IVIG, but with only half the dose amount.
- Study Treatment Group 3: Each patient will receive 12 plasma exchanges, all with just albumin.

Study Treatment Groups: Study Visits

Once you join the study, you will be asked to continue your participation for up to 14 months. During that time you will be scheduled for:

- 6 weeks of intensive treatment, with one full plasma exchange per week
- 12 monthly plasma exchanges with albumin

During your office visit, your Study Team will also take your vital signs (blood pressure, heart rate, respiratory rate, and body temperature) for your safety. You must stay in the study doctor's office for the entire exam to make sure that you are safe to return home. The study doctor will also record any side effects you might have while receiving the study treatment.

Control Group: Study Visits

If you are assigned to the control group, you will have the same visit schedule and study procedures as the study treatment groups. But you will not receive the investigational study drug albumin.

While participating in the AMBAR study, your study doctor will collect information about you as described in the ICF you signed. Your study doctor will also record any side effects you might have while participating in the study.

For the Caregiver

We recognize the valuable role a caregiver (or family member) has for a person with Alzheimer's disease. For the AMBAR study, we will want your feedback. We ask that caregivers (or family members) complete questionnaires used to measure patients' thinking, behavior and functioning. Caregivers (or family members) must also attend each study visit with the enrolled patient.

As you know, there is no cure for Alzheimer's disease. Your participation in AMBAR is essential to help us gather the information needed for this research.

Tips for Study Participation

- ✓ Keep track of all of your appointments for the AMBAR study. You will receive an Appointment Reminder Card at each study visit. Note the next study visit in your paper or electronic calendar. There's also a section in this Study Guide to write down your appointment schedule.
- ✓ Write down any questions or concerns you may have for the AMBAR Study Team. You can write them in this Study Guide, and keep it handy for your next study visit.
- ✓ Make sure you have transportation to each of your study appointments. If you don't drive or no longer drive, make transportation arrangements ahead of time.
- ✓ If any of your contact information changes during your participation in the AMBAR Study, be sure to let your Study Team know.

Study Appointment Schedule

It is important that you keep your regular visits with your study doctor, as well as any other medical professionals that you see. These visits will allow the study doctor to monitor your health and give you and the caregiver a chance to ask any questions.

Keep track of your study visits below.

INTENSIVE THERAPY PERIOD

Week 1 Study Visit

Date/Time:_____

Week 2 Study Visit

Date/Time:_____

Week 3 Study Visit

Date/Time:_____

Week 4 Study Visit

Date/Time:_____

Week 5 Study Visit

Date/Time:_____

Week 6 Study Visit

Date/Time:_____

Week 7-8 Study Visit (cognitive and behavioral tests)

Date/Time:_____

Keep track of your study visits below.

MAINTENANCE PERIOD

Month 3 Study Visit
Date/Time:_____

Month 4 Study Visit
Date/Time:_____

Month 5 Study Visit
Date/Time:_____

Month 6 Study Visit
Date/Time:_____

Month 7 Study Visit
Date/Time:_____

Month 8 Study Visit
Date/Time:_____

Month 9 Study Visit
Date/Time:_____

Month 10 Study Visit
Date/Time:_____

Month 11 Study Visit
Date/Time:_____

Month 12 Study Visit
Date/Time:_____

Month 13 Study Visit
Date/Time:_____

Month 14 Study Visit
Date/Time:_____

Keep track of your study visits below.

ADDITIONAL VISITS (PET/MRI/CATHETER/LUMBAR)

Visit Description:_____
Date/Time:_____

Visit Description:_____
Date/Time:_____

Visit Description:_____
Date/Time:_____

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Visit Description:_____
Date/Time:_____

Date	Question	Answer

Contact Information for the Study

Remember, if you move or change your contact information, it is important to give your new information to your doctor.

AMBAR Doctor's Name:

Study Coordinator's Name:

Office Phone Number:

Office Address:

Thank you for your participation in the AMBAR Study!

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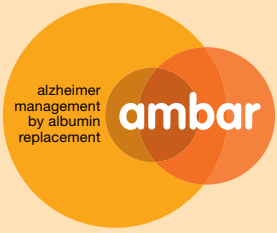

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