

Generation Study 2: Amyloid Disclosure Session

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Study Summary

- The purpose of the study is to determine whether the medication CNP520 is safe and beneficial for people who are at higher risk for onset of dementia due to Alzheimer's disease based on:
 - Age
 - Genetics
 - Presence of an elevated level of a protein called amyloid in the brain

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Study Eligibility: APOE Gene & Amyloid

- As part of screening for this study, you learned your APOE test result.
- Then you had a brain amyloid test.
- If you have one (1) copy of the APOE4 gene, you have to learn your amyloid test result to continue screening for Generation Study 2.
 - In order to continue screening for Generation Study 2, your result needs to show an elevated level of amyloid.
- If you have two (2) copies of the APOE4 gene you can opt out of learning these results and still continue screening for Generation Study 2.

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How is Amyloid Measured?

- In this study, amyloid is measured either by a brain scan or a lumbar puncture.
- The following slides explain how we measure amyloid and interpret the test result.

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What are Amyloid Plaques?

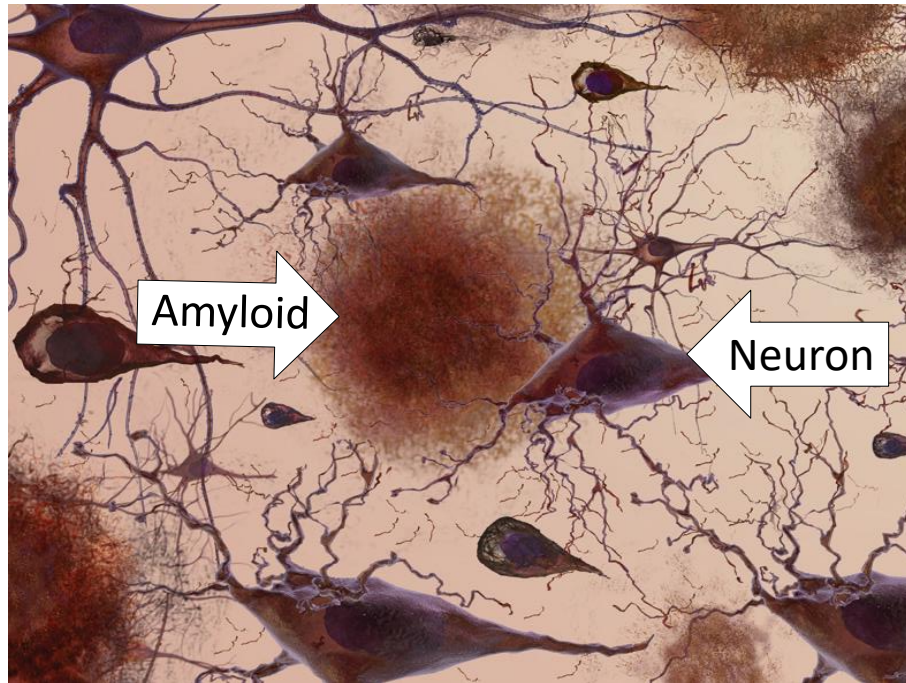


Image reprinted courtesy of the National Institutes of Health, National Institute on Aging

Our brains are made of cells called neurons.

Amyloid plaques are abnormal clusters of a protein that builds up between neurons.

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Amyloid Plaques and Dementia due to Alzheimer's Disease

- Abnormal clusters of amyloid plaques are seen in the brains of persons with dementia due to Alzheimer's disease.
- An elevated level of amyloid is associated with developing memory and thinking problems.
- It is unknown at this time whether elevated amyloid causes the changes in the brain that lead to dementia due to Alzheimer's disease.

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Amyloid and Dementia due to Alzheimer's Disease

- Amyloid plaques build up in areas of the brain typically affected by Alzheimer's disease.
- Build up of amyloid plaques can appear 10 to 15 years before the onset of symptoms.
- Some studies suggest about 30% of older adults without memory and thinking problems have some build up of amyloid plaques.

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Diagnosing Dementia due to Alzheimer's Disease and the Role of Amyloid

- Brain scans, such as Positron Emission Tomography (PET) scans, can detect amyloid.
- Amyloid can also be detected in spinal fluid collected from a lumbar puncture.

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Measuring Amyloid with a PET Scan

- The radiotracer injected before the PET scan “lights up” where amyloid plaques are located.
- The PET scan turns this information into images.
- A qualified and trained expert assesses the images to determine whether the level of amyloid is “elevated” or “not elevated”.

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Measuring Amyloid with a Lumbar Puncture

- A lumbar puncture is a common procedure in which a thin needle is put into the lower part of the spinal column to collect spinal fluid.
- Level of amyloid in the spinal fluid is measured.
- The amount of amyloid in the spinal fluid is used to determine whether the level of brain amyloid is elevated or not elevated.

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About the Amyloid Test Results

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What are the Possible Results of an Amyloid Test?



Elevated
amyloid level

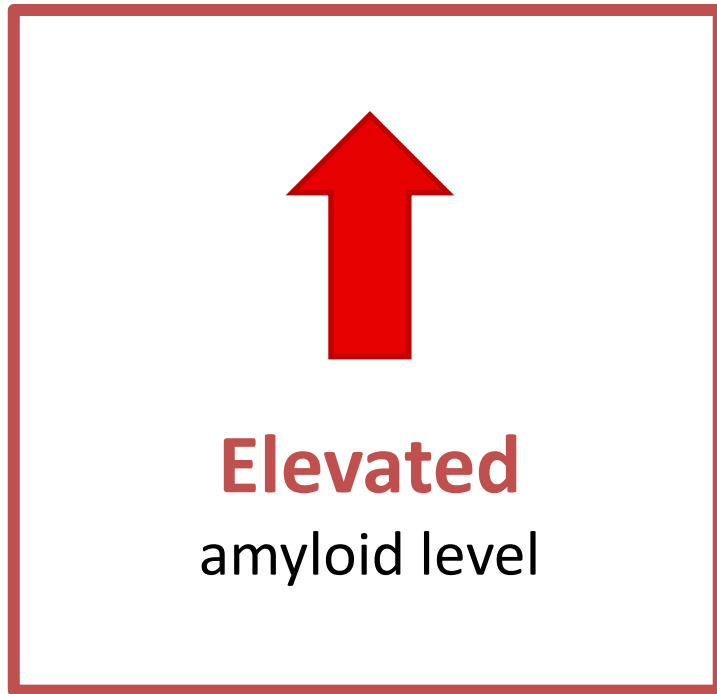


Not Elevated
amyloid level

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A Result that Shows an Elevated Amyloid Level

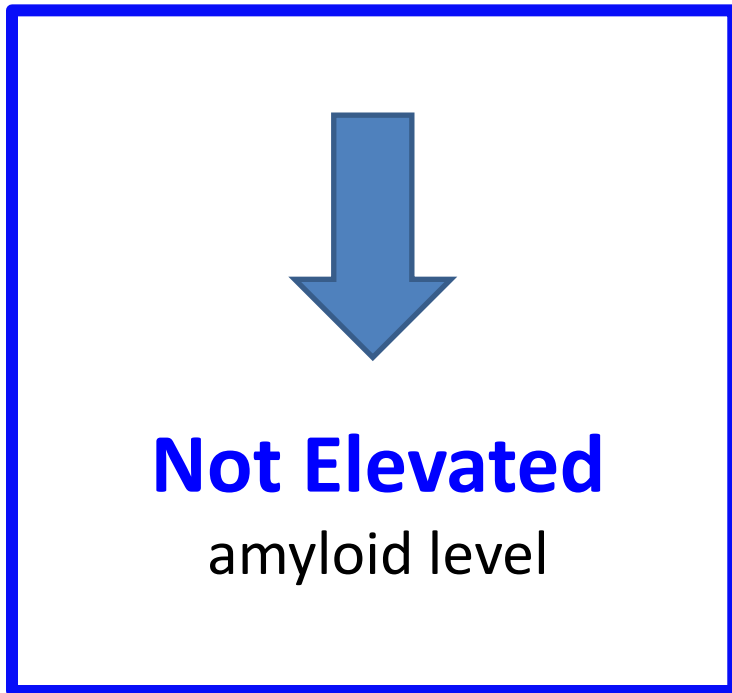


- Having elevated amyloid may increase the risk of developing dementia due to Alzheimer's disease.
- Elevated amyloid does not mean a person will definitely develop dementia due to Alzheimer's disease.

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A Result that Shows a Not Elevated Amyloid Level

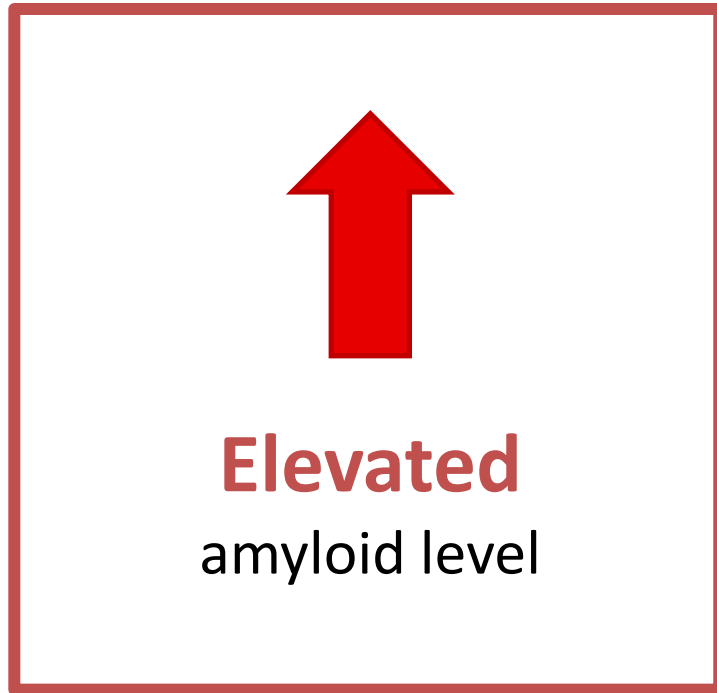


- Amyloid may still be present, but not at an elevated level.
- A person who has a not elevated level could have an elevated level in the future.
- A person who has a not elevated level could still develop dementia due to Alzheimer's disease in the future.

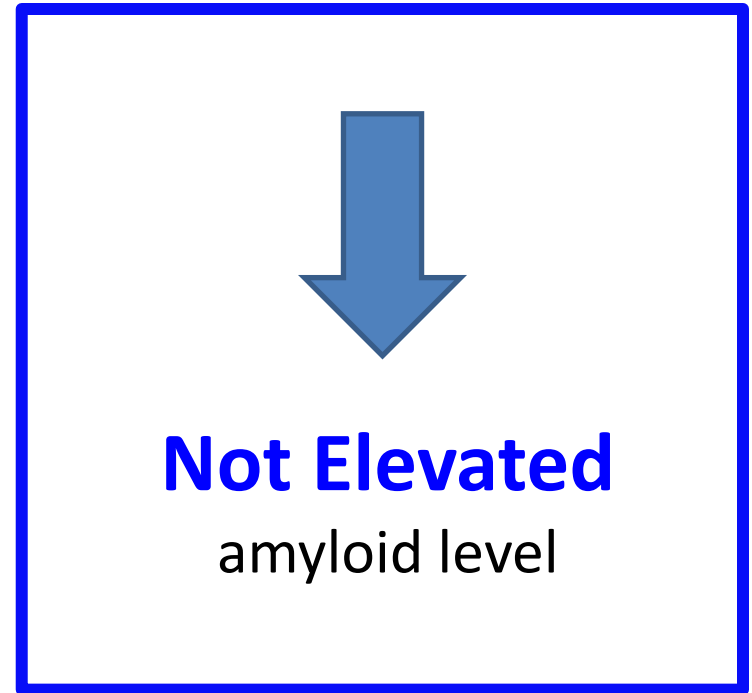
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Amyloid and Dementia due to Alzheimer's Disease



Does not necessarily mean someone will develop dementia due to Alzheimer's disease.



Could still develop an elevated level, or dementia due to Alzheimer's disease in the future.

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Understanding Risk Relationships: Cholesterol as an Example

Cholesterol:

Having high cholesterol increases the risk of having heart disease, but having high cholesterol does not mean a person will definitely have a heart attack.

Amyloid:

Having elevated amyloid may increase the risk of developing dementia due to Alzheimer's disease, but elevated amyloid does not mean a person will definitely develop dementia due Alzheimer's disease.

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Amyloid Test Limitations

- Brain amyloid tests only evaluate the presence of amyloid at the time these tests are done.
- The test result cannot determine whether you will develop dementia due to Alzheimer's disease now or in the future.

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Amyloid Test Limitations

- At present, researchers and clinicians do not have enough information to use a person's amyloid test result to calculate their risk of developing dementia due to Alzheimer's disease.
 - This also means we cannot combine amyloid and APOE test results to estimate risk for developing dementia due to Alzheimer's disease.

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Next Steps

- If you are ready to learn the result of your amyloid test, it will be shared with you now.
 - It is always your choice whether or not to learn your result.
- If you have one copy of the APOE4 gene, you have to learn your amyloid test result to continue screening for Generation Study 2.
 - In order to continue screening for Generation Study 2, your result needs to show an elevated level of amyloid.
- If you have 2 copies of the APOE4 gene you can opt out of learning these results and still continue screening for Generation Study 2.

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Questions?

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