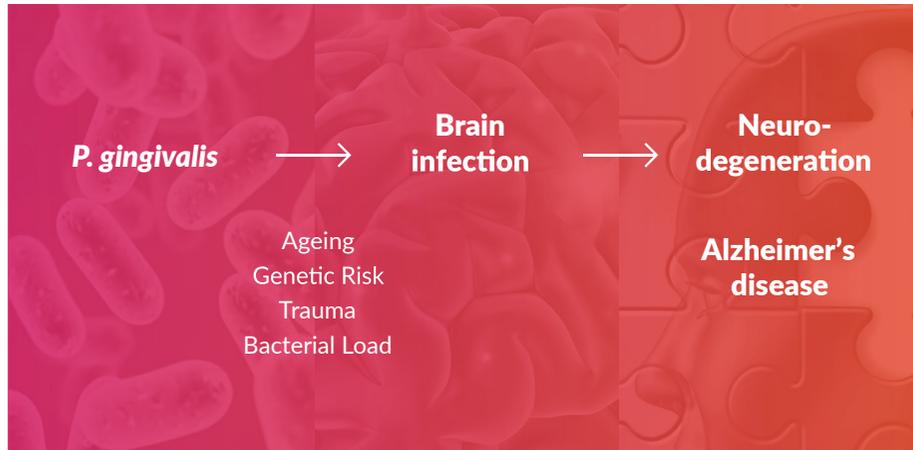


## Bacteria May Cause Alzheimer's

Scientific experts have discovered that a bacteria called *P. gingivalis*, most commonly associated with degenerative gum disease, can infect the brain in older people who are more susceptible to infection. Once in the brain the bacteria releases toxic proteins, called gingipains, that have been shown to destroy neurons and cause other signature signs of Alzheimer's disease in animal studies.



The GAIN (GingipAIN Inhibitor for Treatment of Alzheimer's Disease) Trial will evaluate whether the investigational oral drug COR388 is safe and can slow or halt the progression of Alzheimer's disease by inactivating the toxic proteins, called gingipains, released by the bacteria and stop or slow further damage to healthy brain cells.



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Learn more at [www.GainTrial.com](http://www.GainTrial.com)

*The safety and effectiveness of COR388 for the treatment of Alzheimer's disease have not been established*



Study Sponsor

CORTEXYME



**Do You or Someone  
You Love Have  
Alzheimer's Disease?**

**Consider Participating in  
the GAIN Trial**

GAIN is a clinical trial evaluating whether an investigational oral drug is safe and can halt the progression of Alzheimer's disease by reducing the damage caused by bacteria in the brain. Eligible study participants are being recruited at study sites around the country.

**You or a loved one may be eligible for the study if you:**

- ✓ Are 55 to 80 years old
- ✓ Have been diagnosed with mild to moderate Alzheimer's disease
- ✓ Have a caregiver or family member who will attend study visits, report on daily activities and oversee you taking medication

**Study participation, testing and medication are free to all subjects. Some people may receive stipends to cover meals and travel related to study visits.**

## About The GAIN Trial

The GAIN (GingipAIN Inhibitor for Treatment of Alzheimer's Disease) Trial is based on a growing body of scientific evidence that the bacteria *P. gingivalis*, most commonly associated with degenerative gum disease, can infect the brain and cause Alzheimer's disease.

This clinical trial will evaluate whether the investigational oral drug COR388 is safe and can slow or halt the progression of Alzheimer's disease.

## Participating in GAIN

The GAIN Trial is looking to enrol more than 500 participants with mild to moderate Alzheimer's disease at more than 90 clinical trial centres in the United States and Europe.

Subjects enrolled in the study will be randomly assigned to one of three groups:

- One-third will take an 80 milligramme pill of the study drug COR388 by mouth twice a day
- One-third will take a 40 milligramme pill of COR388 by mouth twice a day
- One-third will take a placebo (sugar pill) by mouth twice a day

In order to scientifically assess the effects of the drug, neither the participants nor the clinical team will know during the study what group each patient is in. Participation in the study will last about one year.

## Selection

If you or a loved one with Alzheimer's disease are interested in volunteering, you will need to go through a screening process.

The investigators at the study sites will review criteria with you to ensure you are an appropriate candidate. You can participate in this study even if you are taking other medication for Alzheimer's disease, if the dose is stable and if you meet the other study requirements.



## What is Involved

### Informed Consent

You and your caregiver or family member will be presented with detailed study information and you will be asked to sign a consent form before any study procedures and assessments are done.

### Screening Visit

You and your caregiver or family member will participate in a screening visit that involves several tests, including brain imaging, blood work, a physical exam, medical history and possibly an oral exam. Several cognitive tests will also be conducted to determine whether you are a candidate for the study. The screening tests may take place over more than one visit.

### Study Group Assignment

Participants in the study will be randomly assigned to one of three groups, two groups will receive different doses of the study drug COR388 pills and one group will receive placebo (sugar) pills.

### Study Initiation

The first day of participating in the study, you will take the first dose of the drug randomly assigned to you and undergo testing. Participants will then take the study drug twice daily until completion of the study treatment period 48 weeks later.

### Study Visits

Participants will attend scheduled visits to the clinic for assessments every four to eight weeks until the 48-week study treatment period is complete. Throughout this period these visits will include memory and psychological assessments as well as physical exams, vital signs, blood work and other safety tests. Most participants will have a lumbar puncture, which is a safe procedure that allows for analysis of biological markers in the brain.

### Follow-up

About six weeks after the study treatment period is complete, participants will have a follow-up appointment at the clinic where final memory assessments and safety tests will be conducted. All eligible participants who complete the one year study may have the opportunity to enrol in a follow-on study in which all subjects receive COR388.

*The safety and effectiveness of COR388 for the treatment of Alzheimer's disease have not been established*