CLINICAL TRIALS WATCH

ACCESSIBLE EASY READ INFORMATION ON:

VALZ-Pilot STUDY
# VALZ-Pilot study

## 1. Study Information

<table>
<thead>
<tr>
<th>Name of the study</th>
<th>Feasibility and Effects of Valaciclovir Treatment in Persons With Early Alzheimer’s Disease</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study sponsor</td>
<td>Hugo Lovheim</td>
</tr>
<tr>
<td>Disease</td>
<td>Alzheimer’s disease</td>
</tr>
<tr>
<td>Phase</td>
<td>Phase II</td>
</tr>
</tbody>
</table>

## 2. Information about the drug that will be tested in the study

<table>
<thead>
<tr>
<th>Name of drug</th>
<th>Valaciclovir</th>
</tr>
</thead>
<tbody>
<tr>
<td>Administration</td>
<td>One to two oral tablets taken three times daily</td>
</tr>
<tr>
<td>Is the drug already on the market for another medical condition?</td>
<td>Yes for the treatment of herpes simplex and herpes zoster</td>
</tr>
</tbody>
</table>

| Will all participants receive the same drug? | All participants will receive a tablet of 500mg the first week and then two tablets of 500 mg week 2-4. |

## 3. Information about participating in the trial

### What are the researchers trying to find out?

- The purpose of the study is to evaluate the effects of Valaciclovir treatment in people with Alzheimer’s disease or mild cognitive impairment of Alzheimer’s disease.

### How long will the treatment last?

- 1 month

### What your involvement will entail?

- During the study, participants will be asked to:
  - Undertake CSF examination (spinal tap) and brain scans (PET)
  - Complete a memory test (MMSE) to assess cognitive function.

  Further information on the number of visits can be obtained from the study team.

## 4. Who can participate in this study?

### Who can participate in the study?

To take part in the study, participants must:
• Be 65 years and older
• Have a score of about 18 points or more in the MMSE test (a test about your memory). This would suggest that the person has an impairment in their memory.

• Have results of brain scans consistent with the clinical diagnosis of Alzheimer’s disease or mild cognitive impairment due to Alzheimer's disease

• Have the Herpes Simplex Virus (measured with blood test after inclusion)

• Have the Apolipoprotein E allele 4 carriage (fat-binding protein implicated in Alzheimer's disease) (measured with blood test after inclusion)

• If the person is taking medication including medication for Alzheimer's disease (rivastigmine, galantamin, donepezil or memantine), the dosing regimen must have been stable for at least one month

• Have no allergy against valaciclovir

• Have an ability to comply independently the study or have a study partner who has a sufficient contact with the participant.

Who cannot participate in the study?

Exclusion criteria include:

• Renal disorder

• Currently taking anticoagulants

• A disease or a medical condition that may interfere with the safety or study assessments including cancer and heart failures

• Any other type of dementia and neurological disease that is not Alzheimer’s disease (including vascular dementia, brain tumor, multiple sclerosis)

• Major depressive episode or other psychiatric illness that
require treatment

- History of alcohol or drug abuse

The above list is not exhaustive. It includes the most common conditions and diseases that might exclude people from the study.

5. Where and when will the study be conducted?

<table>
<thead>
<tr>
<th>European country involved in the trial</th>
<th>Sweden</th>
</tr>
</thead>
<tbody>
<tr>
<td>Estimated start date of recruitment</td>
<td>December 2016</td>
</tr>
</tbody>
</table>

6. Information for your doctor

<table>
<thead>
<tr>
<th>EudraCT Number:</th>
<th>2016-002317-22</th>
<th>Clinicaltrials.gov identifier</th>
<th>NCT02997982</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study contact information</td>
<td>Hugo Lövheim +46702979499</td>
<td><a href="mailto:hugo.lovheim@umu.se">hugo.lovheim@umu.se</a></td>
<td></td>
</tr>
<tr>
<td>Link to full text</td>
<td><a href="https://clinicaltrials.gov/ct2/show/NCT02997982">https://clinicaltrials.gov/ct2/show/NCT02997982</a></td>
<td></td>
<td></td>
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</tbody>
</table>

✓ The information contained in this document is based on information available on public registries (e.g. clinicaltrials.gov website) on January 2019.

✓ This document has been reviewed by the pharmaceutical company running this trial.

✓ This document has been reviewed by a member of the European Working Group of People with Dementia.