Axona dosage compliance markedly increases efficacy

Patients who consumed at least 80% of the total Axona dose over 90 days experienced the greatest improvement.

• Even small changes in ADAS-Cog scores are associated with a measurable effect on activities of daily living (particularly personal care) and the amount of time caregivers spend assisting patients with these activities.

Mean change in ADAS-Cog scores from baseline for ITT, per protocol, and dosage-compliant populations, stratified by APOE4 carriage status.

<table>
<thead>
<tr>
<th>APOE4 Carriage Status</th>
<th>ITT w/LOCF</th>
<th>Per Protocol</th>
<th>Dosage-Compliant</th>
</tr>
</thead>
<tbody>
<tr>
<td>E4(+)</td>
<td>-2.426</td>
<td>1.227</td>
<td>0.956</td>
</tr>
<tr>
<td>E4(-)</td>
<td>-1.182</td>
<td>1.614</td>
<td>0.989</td>
</tr>
</tbody>
</table>

Axona® is a prescription medical food intended for the clinical dietary management of the metabolic processes associated with mild to moderate Alzheimer’s disease.

Alzheimer’s Disease Clock Draw Test Workbook

The clock draw test (CDT) can be utilized as a screening and evaluation tool for impairments in visuocognitive and executive function. This quick test can help you assess the progress of your patients during Alzheimer’s disease therapy.

Instructions

Read the following instructions to your patients:

1. Using the space provided on your worksheet, I would like you to draw the face of a clock. When you are done, please put in all the numbers and set the hands at twenty minutes past eight o’clock.

Please note: The room in which the patient is asked to draw a clock should not contain a clock.

Scoring

The CDT is evaluated on a 5-point (0-4) scale, with 0 indicating the lowest level of function.

- Draws closed circle: Add 1 point
- Includes all 12 correct numbers: Add 1 point
- Places numbers in correct positions: Add 1 point
- Places hands in correct positions: Add 1 point

Examples of clock drawings

No-cognitive impairment

<table>
<thead>
<tr>
<th>A</th>
<th>B</th>
<th>C</th>
<th>D</th>
<th>E</th>
</tr>
</thead>
<tbody>
<tr>
<td>CDT score: 2</td>
<td>MMSE score: 29</td>
<td>CDT score: 2</td>
<td>MMSE score: 29</td>
<td>CDT score: 2</td>
</tr>
</tbody>
</table>

Cognitive impairment

<table>
<thead>
<tr>
<th>A</th>
<th>B</th>
<th>C</th>
<th>D</th>
<th>E</th>
</tr>
</thead>
<tbody>
<tr>
<td>CDT score: 4</td>
<td>MMSE score: 29</td>
<td>CDT score: 2</td>
<td>MMSE score: 29</td>
<td>CDT score: 2</td>
</tr>
</tbody>
</table>

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Administering the clock draw test

The CDT is a simple, quick, and accurate method of testing cognitive impairment in areas that may not be fully evaluated by the mini-mental state examination (MMSE). The test assesses visuospatial and executive functions and may be used as a quick evaluation to detect and track cognitive impairment.

Examples of clock drawings

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Measure patient success

Axona dosage compliance markedly increases efficacy

Patients who consumed at least 80% of the total Axona dose over 90 days experienced the greatest improvement.

Even small changes in ADAS-Cog scores are associated with a measurable effect on activities of daily living. Caregivers spend assisting patients with these activities with a measurable effect on activities of daily living.

The clock draw test (CDT) can be utilized as a screening and evaluation tool for impairments in visuocognitive and executive function. This quick test can help you assess the progress of your patients during Alzheimer’s disease therapy.

Axona® is a prescription medical food intended for the clinical dietary management of the metabolic processes associated with mild to moderate Alzheimer’s disease.

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The CDT is a simple, quick, and accurate method of testing cognitive impairment in areas that may not be fully evaluated by the mini-mental state examination (MMSE). The test assesses visuospatial and executive functions and may be used as a quick evaluation to detect and track cognitive impairment.

Instructions

Read the following instructions to your patients:

1. Using the space provided on your worksheet, I would like you to draw the face of a clock. When you are done, please put in all the numbers and set the hands at twenty minutes past eight o’clock.

Please note: The room in which the patient is asked to draw a clock should not contain a clock.

Scoring

The CDT is evaluated on a 5-point (0-4) scale. Add 1 point for each item:

- Draws closed circle
- Places hands in correct positions
- Places numbers in correct positions
- Contents: Numbers in correct positions

Interpretation

It is unlikely that a cognitively impaired person will be able to draw a perfect clock, and a low score indicates need for further evaluation.

Examples of clock drawings

A: No cognitive impairment

B: Cognitive impairment

C: Cognitive impairment

D: Cognitive impairment

E: Cognitive impairment

Note: Examples of clock drawings by a normal elderly control (A) and patients with dementia (B-E).

For these examples, patients were instructed to draw a clock and the numbers, and then place the hands at the correct time.
Alzheimer’s Disease Clock Draw Test Workbook

The clock draw test (CDT) can be utilized as a screening and evaluation tool for impairments in visualconstructional and executive function. This quick test can help you assess the progress of your patients during Alzheimer’s disease therapy.2,3

Axona® is a prescription medical food intended for the clinical dietary management of the metabolic processes associated with mild to moderate Alzheimer’s disease.1

Administering the clock draw test

The CDT is a simple, quick, and accurate method of testing cognitive impairment in areas that may not be fully evaluated by the mini-mental state examination (MMSE). The test assesses visuospatial and executive functions and may be used as a quick evaluation to detect and track cognitive impairment.6

Instructions2

Read the following instructions to your patients:

1. Using the space provided on your worksheet, I would like you to draw the face of a clock. When you are done, please put in all the numbers and set the hands at twenty minutes past eight o’clock.

Please note: The room in which the patient is asked to draw a clock should not contain a clock.

Scoring2

The CDT is evaluated on a 5-point (0-4) scale.

 Draws closed circle Add 1 point
 Places numbers in correct positions Add 1 point
 Places hands in correct positions Add 1 point

Examples of clock drawings2,4

No-cognitive impairment

Cognitive impairment

A B C D E

Note: Examples of clock drawings by a normal elderly control (A) and patients with dementia (B-E).

For these examples, patients were instructed to draw a clock and the numbers, and then place the hands at twenty minutes past eight o’clock.

Axona dosage compliance markedly increases efficacy

Patients who consumed at least 80% of the total Axona dose over 90 days experienced the greatest improvement.5

- Even small changes in ADAS-Cog scores are associated with a measurable effect on activities of daily living (particularly personal care) and the amount of time caregivers spend assisting patients with these activities.6

Mean change in ADAS-Cog scores from baseline for ITT, per protocol, and dosage-compliant populations, stratified by APOE4 carrier status:

<table>
<thead>
<tr>
<th>Treatment</th>
<th>ITT w/LOCF</th>
<th>Per Protocol</th>
</tr>
</thead>
<tbody>
<tr>
<td>Axona</td>
<td>-0.0312</td>
<td>0.956</td>
</tr>
<tr>
<td>Placebo</td>
<td>1.227</td>
<td>1.076</td>
</tr>
</tbody>
</table>

Mean change in ADAS-Cog scores from baseline for E4(–) ITT, per protocol, and dosage-compliant populations:

<table>
<thead>
<tr>
<th>Treatment</th>
<th>ITT w/LOCF</th>
<th>Per Protocol</th>
</tr>
</thead>
<tbody>
<tr>
<td>Axona</td>
<td>-1.182</td>
<td>1.963</td>
</tr>
<tr>
<td>Placebo</td>
<td>3.854</td>
<td>0.145</td>
</tr>
</tbody>
</table>

Mean change in ADAS-Cog scores from baseline for E4(+) ITT, per protocol, and dosage-compliant populations:

<table>
<thead>
<tr>
<th>Treatment</th>
<th>ITT w/LOCF</th>
<th>Per Protocol</th>
</tr>
</thead>
<tbody>
<tr>
<td>Axona</td>
<td>-2.426</td>
<td>0.833</td>
</tr>
<tr>
<td>Placebo</td>
<td>1.472</td>
<td>0.846</td>
</tr>
</tbody>
</table>

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References:

1. Please see medical food full prescribing information at www.about-axona.com.

2. CONTAINS: MILK AND SOY. Caseinate and whey (dairy), and lecithin (soy).

3. Axona should be used with caution in patients who are at risk for ketoacidosis, for example, patients with a history of alcohol abuse and poorly controlled diabetics; or those who have a history of inflammation of the gastrointestinal system, metabolic syndrome, and/or renal dysfunction. Axona contains protein that may cause allergic reactions, particularly in those who are sensitive to food proteins.