News and Views

A New Treatment for Alzheimer's Disease Gets Full FDA Approval

Lecanemab-irmb, an amyloid beta-directed antibody, marketed by the name of Leqembi, has been granted full approval by the US Food and Drug Administration (FDA) for adult patients with Alzheimer's disease. It is the first such treatment for the treatment of Alzheimer's disease and is administered as an IV infusion once every 2 weeks. Leqembi, which received accelerated approval in January this year, acts by reducing the amyloid plaques in the brain, the hallmark of Alzheimer's disease.

Indication: Patients with mild cognitive impairment or mild dementia stage of Alzheimer's disease.

Contraindication: Hypersensitivity to lecanemab-irmb or to any of its inactive ingredients. The drug should be avoided in advanced stage of the disease.

Adverse effects: Angioedema, anaphylaxis, headache, infusion-related reactions.

Warning and precautions:

- Amyloid-related imaging abnormalities (ARIA) - temporary swelling in brain areas - can occur; symptoms, if they occur, include headache, confusion, dizziness, vision changes and nausea. Rarely, life-threatening brain edema or intracerebral hemorrhages can occur.
- Patients should be closely monitored via brain imaging.
- Patients should be investigated for ApoE ε4 before initiating treatment as patients who are homozygous for the ApoE ε4 allele are at greater risk of developing serious and severe ARIA.
- Exercise caution when using this drug in patients on anticoagulants or other risk factors for intracerebral hemorrhage.

(*Source: FDA News Release: FDA converts Novel Alzheimer's disease treatment to traditional approval. July 06, 2023. https://www.fda.gov/news-events/press-announcements/fda-converts-novel-alzheimers-disease-treatment-traditional-approval. Accessed July 8, 2023.*)

Prompt Treatment of Endometriosis Improves Quality of Life

Endometriosis has a significant impact on the quality of life for the affected women. To examine the interrelationship between health-related quality of life (HRQoL) and endometriosis, researchers from The University of Queensland examined 3,728 women using data from the Australian Longitudinal Study on Women's Health.[1]

The 36-item Short Form Survey (SF-36) was utilized to assess the HRQoL every 3 years over a period of 22 years from 1996 to 2018. SF-36 covers eight domains: physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotion and mental health function. Women who scored below the 25th percentile had lower HRQoL and those who score above the 25th percentile had higher HRQoL. Endometriosis was classified as clinically suspected endometriosis (self-reported) or surgically confirmed endometriosis.

Analysis of data over the eight surveys revealed a poorer HRQoL in women with endometriosis during the course of the study with worse scores on all the eight domains of SF-36. The odds ratio (OR) for worse scores on all the eight domains were found to be 1.33 for physical functioning, 1.57 for role physical, 1.65 for bodily pain, 1.61 for general health, 1.38 for vitality, 1.38 for social functioning, 1.19 for role emotion and 1.32 for mental health. "Women with endometriosis also had significantly lower physical health 1.68 and mental health components scores 1.28" noted the authors.

This study highlights the impact of endometriosis on mental, physical and social well-being and function of the women with endometriosis compared to those without endometriosis. The strongest association was observed between endometriosis and bodily pain. Next came general health and role physical. Endometriosis-related pain and associated anxiety, stress and depression have been hypothesized to be the underlying reason for the association between endometriosis and HRQoL.

"Our findings highlight the importance of early diagnosis of endometriosis and managing the patients promptly with pain and psychological treatment to boost their quality of life" concluded the authors.

Reference

1. Gete DG, et al. Impact of endometriosis on women's health-related quality of life: a national prospective cohort study. Maturitas. 2023;174:1-7.

Both Optimal Sleep and Higher Physical Activity Vital for Better Cognitive Health

Poor sleep may offset the protective effects of physical activity on cognition in older adults, according to a new study from the University College London, UK published in the journal *Lancet Healthy Longevity*.

To investigate the impact of sleep and physical activity on cognition, researchers examined data of 8,958 participants, aged 50 to 95 years. From the English Longitudinal Study of Ageing collected from January 2008 through July 2019. Episodic memory was assessed every 2 years, for a median follow-up of 10 years, via immediate and delayed recall tasks and verbal fluency with an animal naming task. None of the participants had any cognitive impairment at the time of recruitment. Based on both frequency and intensity of activity, physical activity was categorized as lower or higher physical activity; sleep duration was categorized as short (<6 hours), optimal (6-8 hours) or long (>8 hours). People with self-reported dementia and who were found to have some cognitive impairment were excluded from the study.

At baseline, participants who were less physically active and those with suboptimal sleep performed poorly on cognitive tests. Those who were more physically active and had optimal sleep scored higher on cognitive assessment versus combinations of lower physical activity and sleep categories. The baseline cognitive performances among participants with higher physical activity in the various sleep categories were comparable. After 10 years, decline in cognition was rapid even among participants in the higher physical activity group who slept for less than 6 hours compared to those who slept for 6 to 8 hours. Their cognitive scores were similar to those who were less physically active. When data was analyzed based on sex, long sleep was associated with a more favorable cognitive trajectory among men only. The cognitive benefits of combination of higher physical activity and long sleep were more evident in men. In this study, both optimal sleep and higher physical activity had an independent association with better cognitive function, whereas short sleep was associated with faster cognitive decline regardless of physical activity. Based on their findings, researchers concluded that "physical activity interventions should also consider sleep habits, to maximize benefits of physical activity for long-term cognitive health".

Reference

1. Bloomberg M, et al. Joint associations of physical activity and sleep duration with cognitive ageing: longitudinal analysis of an English cohort study. Lancet Healthy Longev. 2023;4(7):e345-53.

Factors Predicting Uncontrolled Asthma

Thirty percent of patients with type 2 (T2)-high or uncontrolled asthma have higher blood eosinophil counts, serum IgE and fractional exhaled nitric oxide (FeNO) levels, suggests a study published in the *Annals of Allergy, Asthma & Immunology*.[1]

This study recruited 133 patients with type 2 asthma, aged ≥18 years; 23 patients had blood eosinophil counts (BECs) ≥300 cells/μL, serum-free IgE ≥120 ng/mL and their FeNO ≥25 parts per billion (ppb). These patients were categorized as Group 1. Eight-seven patients with higher levels of one or two of the biomarkers were put into Group 2, while in Group 3, 23 patients had lower values of all the three biomarkers. The objective of the study was to define optimal cut-off values of markers of T2 inflammation that were predictive of uncontrolled asthma.

Results showed significantly higher levels of sputum eosinophils, blood eosinophil-derived neurotoxin (measured by enzyme-linked immunosorbent assay [ELISA]) and Siglec8+ eosinophils (measured by flow cytometry) but lower forced expiratory volume in 1 second (FEV1) in Group 1 patients. The prevalence of poorly controlled asthma was also higher in this group; 30.4% had uncontrolled asthma, 43.5% had partly controlled asthma, while 26.1% had well-controlled asthma. In Group 2, asthma was well-controlled in 54% and less than 10% had uncontrolled asthma. None of the patients in Group 3 had uncontrolled asthma and 30% having partly controlled asthma. The increase in FeNO levels (54.3 vs. 28.8 in well-controlled asthma) and BECs (786.7 μL vs. 279.1 μL in well-controlled asthma) in patients with uncontrolled asthma was statistically significant. Although nonsignificant, serum IgE levels were higher in uncontrolled asthma (488.2 ng/mL vs. 298.2 ng/mL).

The optimal cut-off values for predicting uncontrolled asthma were found to be FeNO levels of 22 parts per billion, blood eosinophil counts 161.4 cells/L and serum-free IgE levels of 85.9 ng/mL.

Therefore, the determination of cut-off values of the three T2 biomarkers can help to identify patients who need treatment with additional T2 biologics, despite being on maintenance asthma treatment including inhaled corticosteroids.

Reference

1. Woo SD, et al. Biomarkers for predicting type 2-high and uncontrolled asthma in real-world practice. Ann Allergy Asthma Immunol. 2023;S1081-1206(23)00339-3.

Chronic Pain Disorder Associated with Increased Risk of Premature Death

A recent study published in the open-access journal *RMD Open* has shed light on the potentially increased vulnerability of individuals living with fibromyalgia, a chronic pain disorder characterized by widespread pain and fatigue, to early mortality.

The study, conducted by researchers from the Ben-Gurion University of the Negev in Israel, suggested that fibromyalgia may amplify painful sensations by affecting the processing of pain signals in the brain and spinal cord.

To support their hypothesis, the researchers examined the results of 6 relevant studies published between 1999 and 2020 involving a total of 1,88,751 adults who had other co-existing health conditions.

The analysis revealed that individuals with fibromyalgia faced a 27% higher risk of death from all causes than the general population.

The study also showed that the risk of death from cancer was 12% lower among individuals with fibromyalgia than those without the condition. The risk of accident death was only marginally higher (5%).

However, the risk of death from infections, including pneumonia and septicemia, was 44% higher for individuals with fibromyalgia. Furthermore, the risk of death by suicide was more than 3 times higher than the general population. (*Source: https://www.daijiworld.com/news/newsDisplay?newsID=1098732*)

New Study Establishes a Link Between Gum Disorder and Alzheimer's Disease

According to a study published in the *Journal of Neuroinflammation*, researchers have found a link between periodontal disease and the formation of amyloid plaque, a hallmark of Alzheimer's disease.

The study conducted by researchers from the Forsyth Institute in the US revealed a connection between gum disease and changes in brain cells known as microglial cells. They explained that these cells are crucial in defending the brain against amyloid plaque.

The study focused on microglial cells, a specific type of white blood cell responsible for breaking down amyloid plaque. They discovered that when these cells were exposed to oral bacteria, they became overactive and consumed excessive amounts of amyloid plaque.

This finding had a significant implication as it demonstrated the impact of gum disease on overall health.

Gum disease can lead to lesions between the gums and teeth, allowing bacteria to pass through the blood-brain barrier—a protective layer that lines the inner surfaces of blood vessels in the brain—and trigger a response from microglial cells in the organ.

To further investigate this connection, the researchers isolated microglial cells from the brain and exposed them to oral bacteria. This exposure resulted in the overstimulation of microglial cells, leading to neuroinflammation and alteration in the interaction of microglial cells with amyloid plaques. (*Source: https://www.tribuneindia.com/news/health/new-study-links-gum-disorder-to-alzheimers-disease-524805*)

Triple Combination Therapy Enhances Cystic Fibrosis Treatment

A study published in the *European Respiratory Journal* showed that triple combination treatment could produce long-term benefits, such as reduced lung inflammation and the stickiness of mucus in the airways in individuals with cystic fibrosis.

The study led by Prof Marcus Mall and his team, building upon a previous Charite-led study, has investigated the long-term benefits of triple drug combination therapy for patients with cystic fibrosis. The therapy consisted of elexacaftor, tezacaftor and ivacaftor. The therapy was observed to improve lung function and quality of life. The researchers aimed to determine if these positive effects persisted over 12 months or longer. To assess the long-term impact, they analyzed sputum samples collected from the respiratory tracts of 79 adolescents and adults with cystic fibrosis and chronic lung disease. The findings of the study demonstrated that combination therapy led to a reduction in the viscosity of respiratory secretions. Additionally, the treatment resulted in a decrease in lung inflammation and bacterial infections among the patients. (*Source: https://www.hindustantimes.com/lifestyle/health/how-triple-combination-therapy-improves-cystic-fibrosis-study-101689050492826.html*)

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