

Centre of Excellence in Regenerative
Medicine, Immunotherapy and
Biotechnology

Mesencell Alzheimer's Disease Treatment Strategies

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Mesencell Biotech International

Alzheimer's Disease



Prevention



Treatment Strategies

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1. Alzheimer's Disease

Alzheimer's disease (AD) is the most common cause of dementia, accounting for up to 70% of all dementia cases, and is now estimated to be the third leading cause of death, after heart disease and cancer. AD currently affects 5.2 million people in the United States (US), with projected estimates reaching 13.8 million (115 million worldwide) by the year 2050. Amyloid dysfunction is known to be the main pathological reason in around 20 similar diseases: Parkinson, M. Huntington, ALS and Diabetes type 2 among others.

AD is pathologically characterized by amyloid plaques, neurofibrillary tangles and loss of synapses in the brain. Neurofibrillary tangles consist of hyperphosphorylated tau protein while fibrils of the amyloid beta-peptide (Ab) aggregate into amyloid plaques.



2. Early Detection

Amyloid beta (Ab) is a proteolytic product of the amyloid precursor protein (APP) which is sequentially cleaved in an amyloidogenic pathway by beta- and gamma-secretases. Beta-secretase cleaves APP close to the membrane, releasing a soluble APP beta-fragment.

The main enzyme responsible for the production of toxic amyloid beta in the body is BACE1 (Beta site amyloid precursor protein cleaving enzyme number 1).

BACE1 levels in saliva are considered the best biomarker to assess risk for developing AD. Levels of BACE1 in risk patients are high years before the onset of clinical signs.

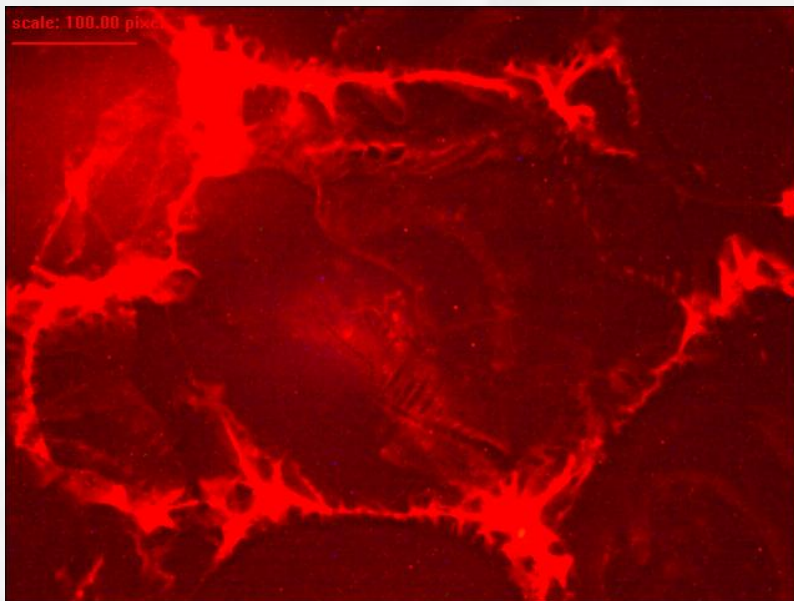
3. Prevention

Prevention of Alzheimer Disease is focused mainly on

- reducing the enzyme BACE1 with the exosomes present in the stem cell derived secretome, preventing further accumulation of amyloid beta
- degradation of existing amyloid beta with Neprilysin
- Neuroprotective activity of brain derived neurotrophic factor BDNF in the secretome
- Neuroprotective activity of glia derived neurotrophic factor GDNF), insulin like growth factor 1 (IGF1) and fractalkine (CX3CL1) in the secretome

Prevention is done by 2-4 times yearly injections of stem cell secretome, produced by mesenchymal stem cells, but injections with the active ingredient in stem cell therapies, i.e. Exosomes, microvesicles and cytokines.

Monitoring via detection of BACE1 levels in saliva.



4. Current Treatment concepts

4.a. Mesenchymal stem cell derived secretome

The secretome of adipose derived MSC consists of various proteins (cytokines), micro & messenger RNA and extracellular vesicles, such as, but not limited to, exosomes and microvesicles.

- Exosomes contain a cargo of micro RNA (miRNA), messenger RNA (mRNA) and cytokines such as Neprilysin.

Exosomes from mesenchymal stem cells contain around

- ✓ 2500 different types of miRNA, all of them are regenerative
- ✓ miRNA 146a for wound healing (diabetes)
- ✓ miRNA 219 and 133b for remyelination (neurology)
- ✓ miRNA 22, 146a, 210 for cardiovascular regeneration

- Microvesicles

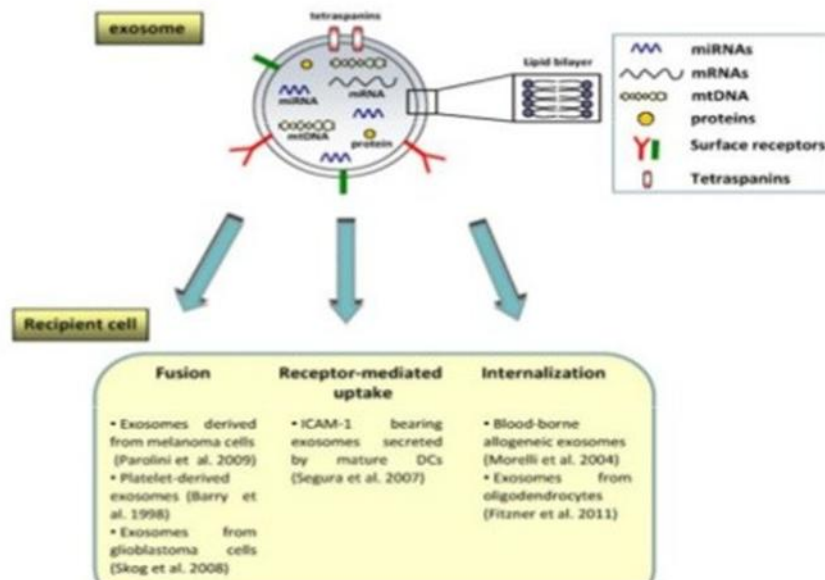
Microvesicles (MVs) released by cells are involved in a multitude of physiological events as important mediators of intercellular communication. MVs derived from mesenchymal stem cells (MSCs) contain various paracrine factors from the cells that primarily contribute to their therapeutic efficacy observed in numerous clinical trials. MVs contain greater amounts of cargo compounds, proteins, and/or RNAs, as well as larger amounts of segregated plasma membrane domains than exosomes. This may increase the possibility of fusion with a target cell that initiates a specific molecular signalling pathway.

- Cytokines

Cytokines are a category of small proteins important in cell signalling. Cytokines are important in health and disease, specifically in host immune responses to infection, inflammation, trauma, sepsis, cancer, and reproduction.

- ✓ Neprilysin: Neprilysin is a zinc metallopeptidase enzyme. The physiological role of Neprilysin depends on its tissue localization. In the brain, neprilysin is involved in degradation of amyloid; specifically, it can degrade the peptide component of Alzheimer's disease. In diabetes, Neprilysin degrades the toxic Islet Amyloid Polypeptide IAPP and thus prevents cell death.
- ✓ HGF: Hepatocyte growth factor (HGF) is an angiogenic molecule that is responsible to promote cell proliferation, resisting apoptosis, and inducing cell motility or invasion
- ✓ BDNF: plays an important role in neuronal survival and growth, serves as a neurotransmitter modulator, and participates in neuronal plasticity, which is essential for learning and memory.

Interaction of exosomes with recipient cells



4.b. Mesenchymal stem cells

Mesenchymal stem cells, or MSCs, are multipotent stromal cells that can differentiate into a variety of cell types, including: osteoblasts, chondrocytes, neurons, muscle cells and adipocytes. This phenomenon has been documented in specific cells and tissues in vivo and in vitro. MSCs are distributed all over the body and are responsible for regeneration. Commonly used tissues for the isolation of MSC are bone marrow, umbilical cord, cord lining and, increasingly, adipose tissue which has a superior amount of MSCs.

In order to apply human autologous adipose tissue derived MSC (ad MSC) in the clinical setting, we have developed a standardized protocol to isolate and culture-expand ad MSC from minimal amounts of fat in vitro, achieving sufficient cell numbers for multiple therapeutic inventions.

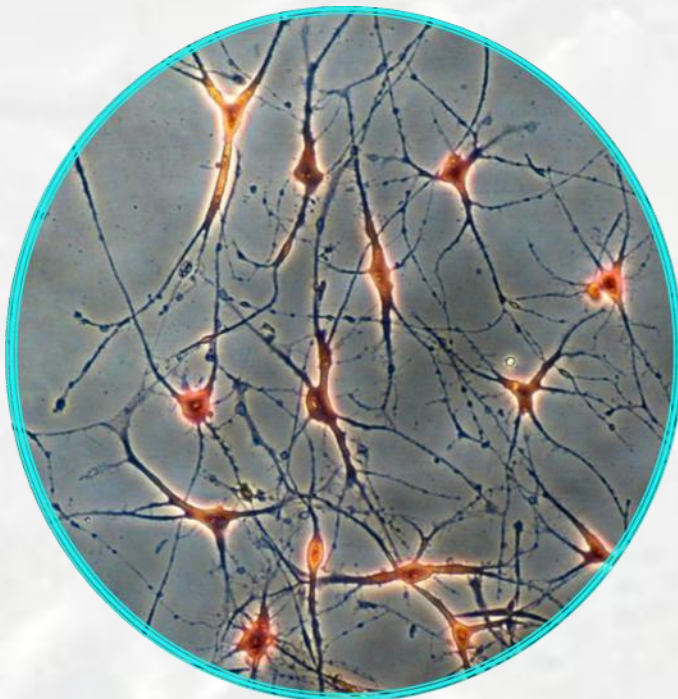
Expanded ad MSCs maintained the potency for effective differentiation independently of donor age and disease status. The confirmed genetic stability and in vivo safety of ex-vivo expanded ad MSCs in animal models and patients indicate that even ad MSCs from older persons are applicable for autologous therapy and are comparable to those derived from young donors.

We investigated the migration ability of ad MSCs and exosomes and their in-vivo homing after systemic infusion and have established several ways to let MSCs produce different kinds of secretome. We are thus able to adjust treatments with the secretome to different diseases as well as to

individual patients. For instance, a simple addition of a vitamin to the stem cell culture media will augment levels of neprilysin in the secretome which then can be used to treat Alzheimer disease patients.

Exosomes and the whole secretome have been used for therapies in regenerative medicine to treat various illnesses such as osteoarthritis, cardiovascular diseases, neurological diseases, pulmonary diseases, diabetes and many more.

We are also able to transform ad MSC into insulin producing cells for the replacement of beta cells of the pancreas and into dopamine producing cells to treat Parkinson disease in the near future. A large body of evidence demonstrated that MSC commonly have immunomodulatory, anti-apoptic and anti-inflammatory properties.



4.c. Intranasal Application of regenerative substances

✓ **BDNF (brain derived neurotrophic factor)**

Brain-derived neurotrophic factor (BDNF) plays an important role in neuronal survival and growth, serves as a neurotransmitter modulator, and participates in neuronal plasticity, which is essential for learning and memory.

✓ **Dihexa (N-hexanoic-Tyr-Ile-(6) amino hexanoic amide)**

Dihexa has been found to potentially assist in the improvement of the cognitive functions that decline as a result of Alzheimer's disease, or other similar dementias, by augmenting synaptic connectivity.

It was found to be more effective than that of brain-derived neurotrophic factor, or BDNF, and has the ability to penetrate the blood-brain barrier.



5. Experimental / Future Treatments

5.a. Anti-GPNMB vaccine with Dendritic Cells

Glycoproteine Non-Metastatic Melanoma Protein B

GPNMB is a molecule with a transmembrane domain that was enriched in senescent cells (Seno-antigen). In preclinical studies, the suppression of GPNMB led to improved normal and pathological phenotypes associated with aging, and extended lifespan. Studies are ongoing to assess a vaccine based on your own Dendritic Cells to remove excess amount of GPNMB from your body.

5.b. GLP-1 peptide injections

Addressing the dysfunctions of all brain cell types in Alzheimer's disease (AD) should cure the dementia, an objective that might be achieved by GLP-1 agonist drugs (glucagon-like peptide-1), because receptors for GLP-1 are present in all of the main brain cell types, i.e., neurons, oligodendroglia, astroglia, microglia, endothelial cells and pericytes.

A recent study of cognition, using GLP-1 agonist, in a randomized, placebo-controlled trial involving 8828 participants, showed significant benefit to cognition.



6. Residential care home for AD patients

There may come a time when the person living with Alzheimer's disease or dementia will need more care than can be provided at home. During the middle stages of Alzheimer's, it becomes necessary to provide 24-hour supervision to keep the person with dementia safe. As the disease progresses into the late-stages, around-the-clock care requirements become more intensive.

Making the decision to move into residential care may be very difficult, but it is not always possible to continue providing the level of care needed at home.

Retirement housing

Retirement housing may be appropriate for individuals in the early stage of Alzheimer's (sometimes referred to as the mild stage in a medical context) who are still able to care for themselves independently. This type of senior housing generally provides limited supervision and may offer opportunities for social activities, transportation and other amenities.

Assisted living (also called board and care, adult living or supported care)

Assisted living bridges the gap between living independently and living in a nursing home. It typically offers a combination of housing, meals, supportive services and health care. Assisted living is not regulated by the federal government and its definitions vary from state to state. Not all assisted living providers offer services specifically designed for people with dementia, so it is important to ask.

Nursing homes (also called skilled nursing facility, long-term care facility or custodial care)

Nursing homes provide around-the-clock care and long-term medical treatment. Most nursing homes have services and staff to address issues such as nutrition, care planning, recreation, spirituality and medical care.

Nursing homes have different staff-to-resident ratios, and their staff members have various levels of experience and training. Nursing homes are licensed by the state and regulated by the federal government.

Alzheimer's special care units (SCUs) (also called memory care units)

SCUs are designed to meet the specific needs of individuals with Alzheimer's and other dementias. SCUs can take many forms and exist within various types of residential care communities, including assisted living, and they may or may not be locked or secured units. Such units most often are cluster settings in which persons living with dementia are grouped on a floor or a unit within a larger residential care building.



When Should Someone with Dementia Go Into a Care Home?

For family members and caregivers, caring for a loved one with dementia can be challenging, particularly as the condition progresses and the symptoms worsen. However, residential dementia care homes and nursing homes can provide a range of benefits to the person living with dementia, helping them to maintain their independence, improve their quality of life, and ensure their safety and well-being stay the top priority.

An ideal time to begin considering a dementia friendly care home would be when either the individual or the carer struggle to provide them the level of independence or support that they deserve. Whether this is due to forgetting to take medication, becoming prone to falls or having an increase in confusion, a care home can provide an environment where those living with dementia can enjoy a better quality of life.

Dementia care in a care home involves providing support and assistance to those living with dementia. This can include help with everyday tasks, such as personal care, dressing, bathing, and eating, as well as providing emotional support and companionship. Some care homes are designed to provide specialised dementia care 24/7 that is tailored to the individual needs of each resident.



What Are the Benefits of Dementia Care?

There are many benefits to receiving dementia care in a care home setting including the following:

Care Unique to Each Individual

Dementia care in a care home is designed to be personalised to the individual needs of each resident. The dementia care team work closely with the resident and their loved ones prior to them moving in to create a personalised care plan tailored to their needs and requirements whilst they support the person on a day-to-day basis.

Residents will be closely monitored to ensure they are always receiving the right care for their needs. Family and friends can visit at any time to continue creating special memories.

A Safe Environment

Care homes provide a safe and secure environment for those living with dementia. This can include secure outdoor spaces, access to emergency response systems, staff trained in managing specific needs and support aids such as rails, walking frames and profiling beds.

In order to ensure residents feel as comfortable as possible, the majority of care homes will include furniture with contrasting colours, signs above doorways, spacious hallways and personalised bedrooms.

Care homes can provide a consistent and familiar environment that can help to reduce feelings of confusion and disorientation for the residents, which makes it easier for them to feel relaxed and focus on a specific task or activity.

Engaging Activities

Care homes typically offer a range of activities designed to benefit residents with dementia. These activities may include memory games, arts and crafts, music therapy, exercise classes, and social events such as movie nights or parties.

Participating in these activities can help residents maintain cognitive function, improve their physical health, reduce feelings of isolation and depression, and enhance their overall quality of life. Additionally, these activities can provide residents with a sense of purpose, help them feel valued and connected to others, and may even help to slow the progression of dementia symptoms.

By providing tailored activities and support, residential dementia care homes can help residents live with greater comfort, dignity, and fulfilment.

A Structured Routine

Many people with dementia benefit from a structured routine, and care homes offer this by providing regular meals, medication management, and daily activities that help residents to maintain a sense of purpose and routine.

A care home will offer a daily schedule of activities which help residents to maintain cognitive function and physical health. Care homes provide regular meals and snacks at set times, ensuring that residents receive proper nutrition and hydration.

A care team will oversee medication management, ensuring that residents take their medication on time and in the correct dosage. Residents can also expect a regular sleep schedule, with set bedtimes and wake-up times. This helps to regulate residents' circadian rhythms and promotes good sleep hygiene, which is important for overall health and well-being.

The logo for Mesencell Biotech, featuring a stylized red 'm' followed by the text 'ESENCELL BIOTECH' in a dark grey, sans-serif font.

Holistic patient care with bioresonance, innovate biomarkers recording cellular activities naturopathy, osteopathy, supplements, hyperbaric treatments, gait analysis as well as conventional laboratory tests.

Mesencell Biotech International's team includes scientists with background in medicine, neurology, sports medicine, aesthetic surgery, biology, molecular biology and biophysics as well as dedicated technicians with a long experience in cell culture and especially in stem cell culture.

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