Efficacy of *Cronassial®* in patients with cognitive dysfunction.

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Objectives and Purpose: Alzheimer's Disease (AD) is characterized by the presence of senile plaques (Amyloid-βpeptide) and the neurofibrillary tangles (hyperphosphorilated tau protein). *Cronassial®* acts through 3 components with neuroprotective effects: *Tramiprosate*, which provides a specific anti-amyloid activity, preventing Aβ peptide aggregation and hippocampus volume loss; *L-Acetyl Carnitine*, which promotes neuronal transmission, N.G.F. activity and myelin sheath integrity through its antioxidant activity; *Glycerophosphorylcholine* and *Choline Bitartrate*, which favor neuronal membranes integrity by increasing phospholipid synthesis, reducing the ischemic damage progression, suppressing free radicals release and improving synaptic transmission. Aim of the present study was to evaluate the efficacy of *Cronassial®* in patients with different grades of dementia.

Materials and Methods: We included a consecutive series of patients attending the Alzheimer Evaluation Unit of the Neurology Department of S. Salvatore Hospital in L'Aquila who accepted to be treated with *Cronassial®*. Inclusion criteria were senile isolated cognitive functions reduction (memory, attention), Mild Cognitive Impairment (MCI), mild to severe AD or subcortical vascular dementia (VaD). Concomitant treatment with AChEI was allowed, provided that they had been started since at least 6 months. The study analyses the disease progression, comparing MMSE, CDR and Rey Memory Test scores at T_0 (before treatment) and T_1 (6-12 months from the beginning of treatment).

Results: We recruited 209 patients attending the Unit, 75 of which were taking *Cronassial®* (32 men – 42.7%, 48 women – 57.3%), with mean age of 72.6 years. The average schooling was 7 years. 26% of patients was affected by MCI, 37.5% by mild AD, 36% by moderate to severe AD and 10.5% by VaD ***(Fig.1)***. In these patients, according to the MMSE follow-up evaluations, there was a minor worsening in patients under treatment with *Cronassial®* (-2 point versus -4 in patients without *Cronassial®* treatment) (p=0.024) ***(Fig.2)***, with an improvement in MCI (+1 point) and a progressive deterioration in the other conditions (-2 in mild AD, -4.66 in moderate to severe AD and -2.88 in VaD) (p=0.008) ***(Fig.3)***. According to the CDR follow-up evaluations, there was an improvement in MCI (-0.37) and mild AD (-0.66) and a disease progression in moderate to severe AD (+0.65) and VaD (+0.27) (p=0.006) ***(Fig.3)***. According to the Rey Memory Test follow-up evaluations there was an improvement in MCI (+5 points) and a progressive deterioration in the other conditions (-2.20 points in mild AD, -7 in medium to severe AD and -0.3 in VaD) (p=0.006). In patients under treatment there was also an improvement of apathy symptoms ***(Fig.4)***.

Conclusion: Patients treated with *Cronassial®* showed an improvement in the follow-up evaluations with a stabilization of cognitive functions, especially in the early stages of decline (MCI and mild AD). Therefore, it can be considered an interesting treatment for its potentially modifying disease action, alone but especially in combination with conventional therapy, and as a preventive measure at the onset of the first warning symptoms. It also allows an extensive use in various clinical pictures (VaD and apathy).

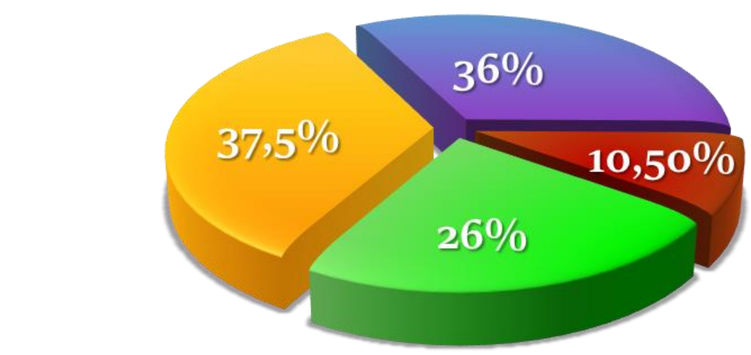

Fig. 1: Types of Dementia in the patients under treatment with *Cronassial* ®.

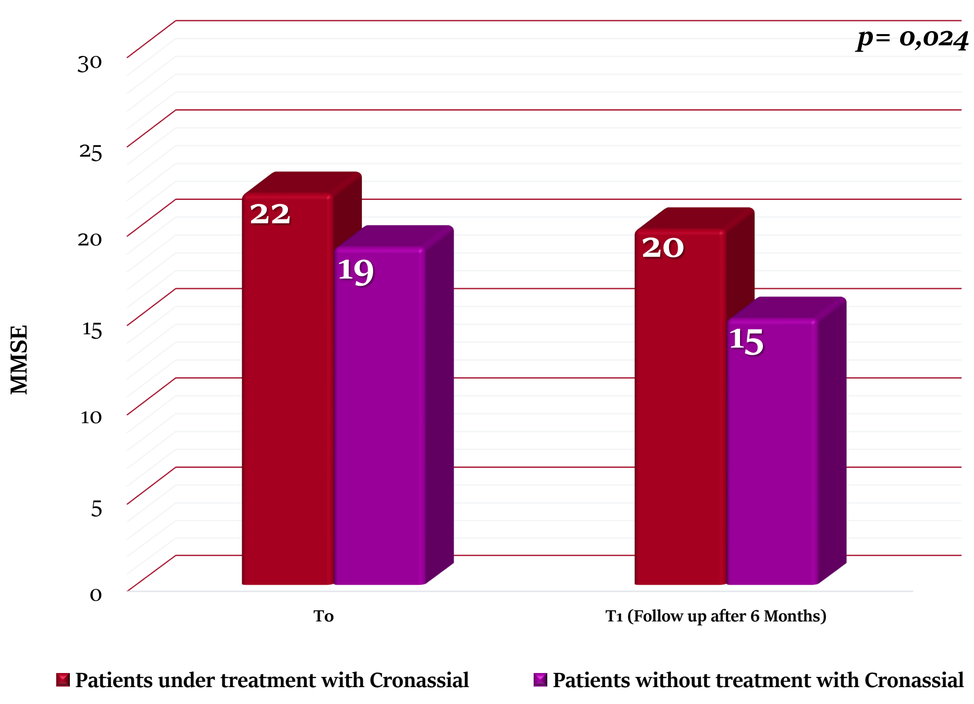

Fig. 2: MMSE evaluations in patients with and without treatment with *Cronassial* ®.

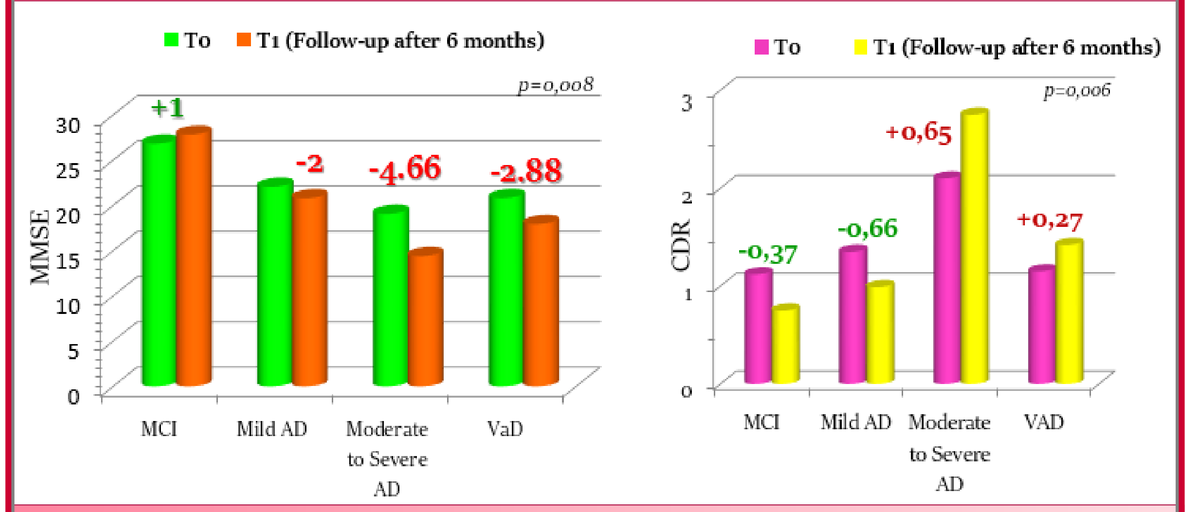

Fig. 3: Follow-up MMSE and CDR evaluations according to different types of Dementia.

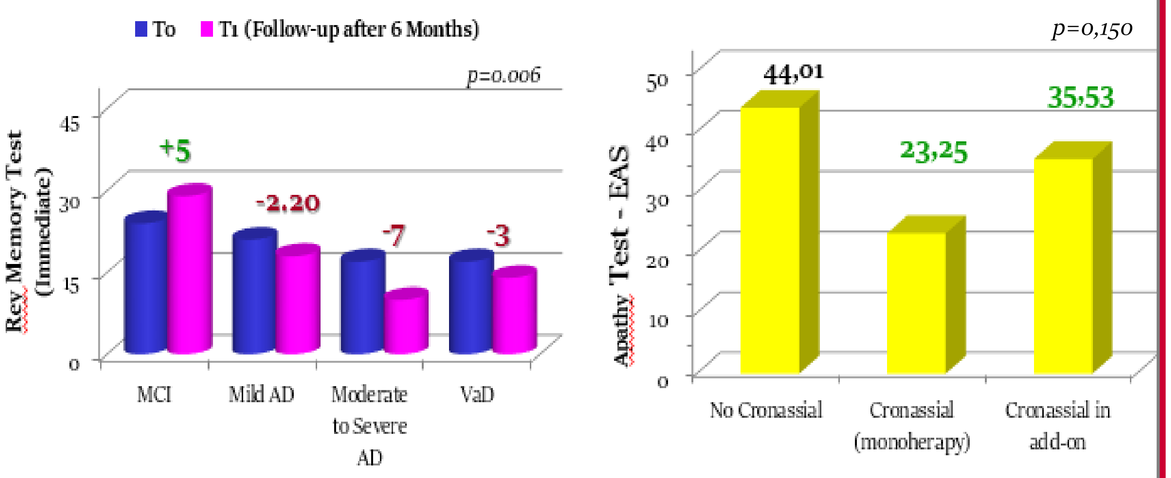

Fig. 4: Follow-up Rey Memory Test (Immediate) evaluations according to different types of Dementia and Apathy Test evaluations in patients under treatment with *Cronassial* ® and not.

References: **1)** Aisen PS, Gauthier S, Ferris SH, et al. *Tramiprosate in mild-to-moderate Alzheimer's disease – a randomized, double-blind, placebo-controlled, multi-centre study (The Alphase Study).* Archives of Medical Science. 2011; 7, 1: 102-111. **2)** Spalletta G, Cravello L, Gianni W, et al. *Homotaurine effects on Hippocampal Volume Loss and Episodic Memory In Amnestic Mild Cognitive Impairment.* Journal Alzheimer's Disease. 2016; Jan 12;50(3):807-16. **3)** Caltagirone C, Ferrannini L, Marchionni N, et al. *The Potential Protective Effects of tramiprosate against Alzheimer's disease: a review.* Aging Clinical and Experimental Research. 2012 Dec; 24(6):580-7.

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