

LETTER ADDRESSED TO PATIENTS OF ALS LIVING ABROAD OF SPAIN, INTERESTED IN CLINICAL TRIAL “CMN/ELA” (EudraCT: 2006-003096-12) DEVELOPED IN MURCIA- SPAIN

Dear friend,

First of all, let us praise your interest in our Clinical Trial. We really appreciate the support expressed in our ongoing work, especially by those that are suffering the tragic impact of a devastating disease as ALS. These human quests to fight suffering are the ones that revive our commitment with the goal that guides our work: try our best in contributing to develop a better future for our patients.

But unfortunately the process of advancing knowledge and creating new therapeutic alternatives does have some stringent conditions that are tough for all those that become involved in this task. That’s what separates science and meaningful knowledge, that advances our resources and capabilities in medicine, from quackery and the despicable attempts of taking advantage of people suffering and in need.

This said, and going back to our study, as you may have already read at clinicaltrials.gov, our protocol has a significant number of interactions with several healthcare professionals, being really challenging for some of the tests and/or interactions not to be produced in Spanish. Also includes a stringent two years’ follow up with visits every 3 months and frequent phone calls. The visits include a thorough examination with Magnetic Resonance, spirometry, neurophysiological workup, etc. You should also take into account that being our study a randomized control trial, one participant may be allocated in the placebo arm during this period. For this reason, although we would be willing to include any patient who asks so and meets the inclusion criteria, we are forced to only accept patients that are able to live near Murcia (Spain) for those two years. We are making a huge effort to keep this protocol moving forward and we cannot expose our collaborators and our funding sources to very high chances of losing a relevant number of follow ups that will compromise the overall effort and results. Although a research protocol may be international, we develop our work in a public regional tax-funded Healthcare system, and therefore we have a main clinical commitment to treat our local patients. Although we know that there might be patients who would cover the expenses of the treatment, to include self-financing patients might affect the objectivity of the trial, risking a potential bias in the results. Therefore being the Clinical Trial in itself free of charge, other expenses of transport, lodging, etc., are obviously on behalf of the patient and their support structure.

We really know that these are a quite severe set of conditions, and we apologize for any annoyance this may cause. But we think that we have to enforce them to ensure the reliability of the trial and its results. It is only by obtaining reliable knowledge that the lessons coming

out from this trial may hopefully lead to feasible alternatives of treatment that eventually will become available to more ALS patients. Going through flawed shortcuts, as tempting as it may appear, would only risk exploitation and chasing false hopes.

Hoping for the best for you in enduring your circumstances, yours faithfully,

Dr. José M^a Moraleda,
Leader of the Research Team
on behalf of the researchers

Dr. Javier Júdez
R&D Area Manager – FFIS
on behalf of the Sponsoring Healthcare
institutions