Nutrition and Healthy Aging 4 (2017) 193–194
DOI 10.3233/NHA-170001
IOS Press

Clinical Trials Corner

Dear Readers,

Welcome to the first edition of the Clinical Trials Corner of *Nutrition and Healthy Aging*. The aim of this section is to inform readers of upcoming clinical trials and highlight new findings. If you would like to draw attention to a specific topic and clinical trials, please email me at: leonie.heilbronn@adelaide.edu.au

Interest in nicotinamide riboside (NR), a putative anti-aging nutritional supplement, is building with recent basic discoveries of improvements in mitochondrial homeostasis, boosts to longevity, and protection from diet induced obesity in mice [1-3]. Recently published studies [1, 2] have shown that NR increases NAD+ and NAD metabolites in healthy adults. There are now a number of clinical trials registered that are recently completed, or currently underway, to determine whether the metabolic health benefits of NR that have been observed in mice will translate to humans.

In October 2016, investigators at the University of Colorado, together with ChromaDex Inc, completed a double blind randomised, placebo controlled, trial to determine the safety of twice-a-day supplementation with NIAGEN™ (500mg) for 6 weeks of in healthy older individuals[(A)]. Secondary outcomes included physical and cognitive function, systemic inflammatory markers, and endothelial function. Results from this trials have not yet been released.

A Phase 2 trial examining three doses of NIAGEN™ (100mg, 300mg, 1000mg) in 140 middle aged overweight healthy adults on urinary methylnicotinaide, and blood, urinary and muscle levels of NR metabolites, resting energy metabolism, branched chain amino acids and adverse events is also underway, and is slated for completion in December 2016[(B)].

Competitors at Elysium Health have also completed a randomised placebo controlled Phase 1 trial to test the safety of 8-weeks supplementation of BASIS™, which combines NR with Pterostilbene, at either the recommended dose (250 mg NR and 50 mg pterostilbene), double the recommended dose, or a placebo daily for the eight-week trial[(C)]. The study enrolled 120 older adults and secondary outcomes include physical performance, body weight, blood lipids, blood glucose, quality of life, and NAD+ levels. The trial was completed in July 2016, and a press release on December 6, 2016 reported no serious adverse events, and a 40–90% increases in blood NAD+ levels.

Thus, NR supplementation will boost NAD+ levels in humans, and we await peer reviewed publications to ascertain whether this will have downstream impacts on markers of metabolic health.

Sincerely,

Leonie K. Heilbronn
Editor, Clinical Trials Corner
Adelaide Medical School, The University of Adelaide,
SAHMRI, Adelaide, Australia.

References

[1] Zhang et al. NAD+ repletion improves mitochondrial and stem cell function and enhances life span in mice. Science. 2016;352:1436.
[2] Trammell et al. 2016 Nicotinamide riboside is uniquely and orally bioavailable in mice and humans. Nature Communications. 2016;7:12948.
[3] Canto C. et al. The NAD+ precursor nicotinamide riboside enhances oxidative metabolism and protects against high fat diet induced obesity. Cell Metab. 2012;15:838-47.

ISSN 2451-9480/17/$35.00

https://www.clinicaltrials.gov/

A). Study Title: Safety and Efficacy of Nicotinamide Riboside Supplementation for Improving Physiological Function in Middle-Aged and Older Adults.

Clinicaltrials.gov identifier: NCT02921659;

Sponsor: University of Colorado, Boulder.

Collaborator: ChromaDex, Inc

Primary Outcome: Incidence of treatment emergent adverse events [Time Frame: 6 weeks], self-reported side effects, vital signs, hematology, liver enzymes, markers of kidney function and blood chemistry.

B). Study Title: A Randomized, Double-blind, Placebo Controlled Parallel Study Investigating the Effects of Niagen™ (Nicotinamide Riboside) on Niagen™ Metabolites in Healthy Adults.

Clinicaltrials.gov identifier: NCT02712593;

Sponsor: KGK Synergise Inc;

Collaborator: ChromaDex, Inc

Primary Outcome: Change in Urinary Methylnicotinamide [Time Frame: 8 weeks]

C). Study Title: A Randomized, Double-blind, Placebo Controlled Study to Evaluate Safety and Health Benefits of Basis™ Among Elderly Subjects.

Clinicaltrials.gov identifier: NCT02678611

Sponsor: KGK Synergise Inc;

Collaborator: Elysium Health

Primary Outcome: Blood pressure [Time Frame: 8 weeks], Safety Blood Parameters, [CBC, electrolytes (Na, K, Cl), kidney function (creatinine), liver function (AST, ALT, GGT and bilirubin)]; Heart Rate