

A clinical Study of Effects of Enhansa ®(enhanced absorption curcumin) on Immunologic and Cognitive/Metabolic Disorders – An overview of results

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Abstract: This is a clinical study of results of the use of Enhansa ® in adults and children with Autism Spectrum and other cognitive, metabolic, immune, and gastrointestinal problems. Enhansa®, is an established widely used oral botanical substance, and it is a turmeric derivative from the botanical curcuma longa, a substance used as a spice from the ginger family (and is therefore legal for SCD-type diets). It has been employed by physicians and pharmacists by prescription and over-the-counter for years with an excellent safety profile.

All subjects used the **Ramped Protocol** for Enhansa dosing, see attachment. Reason(s) for using Enhansa® for entering subjects included cognitive, immune, GI, metabolic, or pain, eg those of autism, AD/HD, PANDAS, other autoimmune diseases, frequent debilitating infections, chronic diarrhea, liver support, arthritis, fibromyalgia, chronic fatigue, need for antioxidants, and control of inflammation.

Labs: dates & results of **both** Baseline & Post-use labs, ie 2 sets of reduced (unoxidized) blood glutathione level, CBC/Diff, CMP, & full OAT urine testing

Introduction

Enhansa ® is an oral enhanced-absorbed curcumin compounded. It is third-party certified to be toxin free, of heavy metals and of petrochemicals and it is not a phosphorylated product.

Twenty two subjects were enrolled in this controlled study. See attached results and dosing protocol. All subjects were ambulatory.

Data includes labs and clinical assessment taken for the baseline parameters before starting Enhansa ®, including blood glutathione levels, CBC/diff & platelets and a full organic acid testing, along with cognitive/behavioral, language, pain/arthritis, gastrointestinal, and liver/metabolic symptoms. The same parameters were reassessed at day 22 of use of Enhansa ®, while symptoms above were assessed during the 22 day period. No other treatments were changed nor initiated during the study period for any subject.

Clinical results in this study include improved

language, reduction of developmental delay issues, increased appetite, calming of mood, heightened immunologic activity, (including some Herxheimer-type responses), and highly significant elevation of blood glutathione levels. There was also a significant reduction in succinic acid in the urine as well as significant normalization of the blood platelets. One adult had a flare of IgA nephropathy and dropped out of the study. Another adult had improvement of lung function (pulmonary fibrosis) and a reduction in pain (chronic pain syndrome). See attached results. No leucopenia nor liver dysfunction occurred.

Blood glutathione is a fundamental, extremely important, natural antioxidant and detoxifier within the body. Persons with immune and developmental problems have low glutathione. Succinic acid is a urine marker for both yeast in the gi tract, and it is also a marker of weak metabolism. Blood platelets, when high, are an “acute phase reactant,” ie they are a sign of immune function and inflammation (similar to a high fever).

Enhansa ® Project Study (2011)

Highly significant laboratory improvements. See associated clinical improvements (attached)

Blood Glutathione Levels			
Highly significant rise w/ Enhansa use			
subject #	pre use	during	difference
1	250	1150	900
2	430	630	200
3	728	856	128
4	625	679	54
5	349	714	365
6	409	538	129
7	475	1248	773
8	1181	1411	230
9	1892	1999	107
10	781	967	186
11	838	986	148
12	1124	898	-226
13	791	910	119
14	1267	1331	64
15	518	864	346
16	698	1001	303
17	864	965	101
18	857	831	-26
19	818	841	23
20	895	1049	154
21	1145	1124	-21
22	893	951	58

t= 3.543: significant @ < 0.0001 and > 99.80 % confidence level

Succinic Acid Levels			
Highly significant decrease w/Enhansa use			
subject #	pre use	during	difference
1	4.5	43	-0.2
2	73	11	-62
3	20	5.3	-14.7
4	9.5	3.9	-5.6
5	25	12	-13
6	43	17	-26
7	46	16	-30
8	17	17	0
9	5	8.7	3.7
10	12	18	6
11	2.4	7.8	5.4
12	11	7.4	-3.6
13	32	9.1	-22.9
14	1.6	1.8	0.2
15	8.4	15	6.6
16	0.7	1.7	1
17	78	25	-53
18	5.7	3	-2.7
19	3.3	18	14.7
20	4.9	1.5	-3.4
21	3.2	3.6	0.4
22	13	20	7

t= -2.109: significant @ <0.025 and >95% confidence level

Platelet Levels			
Highly significant normalization w/Enhansa use			
subject #	pre use	during	difference
1	276	286	10
2	472	521	-49
3	229	222	7
4	213	173	40
5	387	328	59
6	550	364	186
7	262	294	32
8	312	312	0
9	307	297	10
10	228	268	40
11	243	230	13
12	309	348	-39
13	349	351	-2
14	237	245	8
15	242	266	24
16	263	236	27
17	460	297	163
18	145	186	41
19	215	230	15
20	229	256	27

t= 2.470: significant @ <0.025 and > 95% confidence level

Reports from Patients while on Enhansa

- increased appetite noted; significant improvement with attention and focus reported by teacher;
- more attentive while watching TV; for the first time responded correctly to the question “what is your name”; teachers have noted he is learning something everyday; more receptive to potty training; more connected to surroundings; happier; calmer; improved vocabulary; positive experience on Enhansa;
- throat clearing and huffing tics are gone;
- increase speech; less stimming; more eye contact; good mood; good behavior at school; reading all the signs in the house; big time talking and answering questions;
- happy; good day; more energy; hip pain got better and better now almost nonexistent;
- trying to reach the counter, said “I can’t reach” , big deal for her to verbalize that; initiated saying hi to sister and “hi mommy”, normally she doesn’t do that;
- stool is formed for the first time in a long time; calmer, less hyper; he said he was happy this morning; having good days; still formed stool;
- initially temper tantrum, very grumpy; seems less depressed; now better able to express her feelings; much better mood, less whining;
- facial pain from previous infection gone; cold sores decreasing; forehead rash cleared up;
- slight, clear runny nose, mild “allergy look” to eyes; then runny nose subsided; correctly named “yellow” and “blue”; very good mood; small bumps on nose gone; good mood, more focused on activities; not as hyper; no observable physical side effects; interactive, good eye contact; remains in a good mood, calm and interactive
- rash around mouth (worse in the pm); day 5 rash more inflamed following pm dose; then awesome verbal sounds in am; calm and verbal; bad bowel movements; said “dada” after hearing someone else say dad

Acknowledgements

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For further information: Contact Phillip C. DeMio, MD, at (216) 901-0441 or Alan Israel, R.Ph., at the Lee-Silsby Compounding Pharmacy at (216) 321-4300.

Ramping/dosage protocol for Enhansa/Curcumin (150 mg. CAPSULES)

**** Get pre-use labs *before* the first dose of Enhansa**

- Days 1-4:** One capsule with breakfast every **other** day
- Days 5-8:** One capsule with breakfast **daily**
- Days 9-12:** Add additional capsule with dinner every **other** day
- Days 13-16:** One capsule with breakfast and one capsule with dinner **daily**
- Days 17-20:** Add additional capsule with breakfast every **other** day
- Days 21-24:** Two capsules with breakfast and one capsule with dinner **daily**

**** Day 22**, get post use labs while continuing Enhansa (you can get the labs before day 22, for example if it's a weekend or if you've stopped the use of Enhansa before day 22)

- Days 25-28:** Add an additional capsule with dinner every **other** day
- Days 29-32:** Two capsules with breakfast, two capsules with dinner **daily**
- Days 33-36:** Add an additional capsule with breakfast every **other** day
- Days 37 and on:** Three capsules with breakfast, two capsules with dinner **daily**

Administration: Enhansa is better absorbed when given with food and it assists with digestion so taking Enhansa with meals is best. Separating daily doses of Enhansa into two doses per day, as evenly split as possible, can help with even distribution and help to minimize side effects.

NOTE: This supplement stimulates the immune system, supports liver cleansing, reduces inflammation, assists the body with the natural production of glutathione and can aid the body in combating yeast and bacteria in the GI tract. Because it can do so much, it also can produce side effects such as yeast and bacterial die-off and viral upheaval and hopefully elimination. This will sometimes cause behavioral and even physical changes in you or your child (such as tantrums, emotional changes, yeasty or bacterial behaviors, changes in stools and you may see colds, low grade fevers and rashes as you or your child's body attempts to eradicate viruses and pathogens in the GI tract). Lots of fluids (preferably purified water) can be helpful to help during this process to eliminate toxins from the body. Additional side effects can include itching, sometimes anxiety and in some cases even belligerence. This supplement can produce sensitivity to direct sun exposure. Please take appropriate sunburn precautions if out in the sun for a prolonged period of time. If side effects become intolerable or of concern, please contact your practitioner for further instructions.

Ramping/dosage protocol for Enhansa/Curcumin (POWDER)

** Get pre-use labs *before* the first dose of Enhansa

Days 1–4: One small scoop at breakfast, one small scoop at dinner every other day

Days 5-8: One small scoop at breakfast, one small scoop at dinner daily
Days 9-12: Two small scoops at breakfast, one small scoop at dinner daily
Days 13-16: Two small scoops at breakfast, two small scoops at dinner daily
Days 17-20: Three small scoops at breakfast, two small scoops at dinner daily
Days 21-24: Three small scoops at breakfast, three small scoops at dinner daily

** **Day 22**, get post use labs while continuing Enhansa (you can get the labs before day 22, for example if it's a weekend or if you've stopped the use of Enhansa before day 22

Days 25-28: One large scoop at breakfast, three small scoops at dinner daily

Days 29-32: One large scoop at breakfast, one large scoop at dinner daily

Days 32-35: One large scoop and one small scoop at breakfast, one large scoop at dinner daily

Days 36 & on: One large scoop and one small scoop at breakfast, one large scoop and one small scoop at dinner.
Stay at this dose until otherwise advised by Dr. DeMio

SMALL SCOOP = 75mg

LARGE SCOOP = 300mg

Administration: Enhansa is better absorbed when given with food and it assists with digestion so taking Enhansa with meals is best. Separating daily doses of Enhansa into two doses per day, as evenly split as possible, can help with even distribution and help to minimize side effects.

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