somaplus™

The OkinawaAll NaturalFood Formula

A PILOT STUDY EVALUATING THE ROLE OF OKINAWA FOOD BEVERAGE POWDER (OFBP) IN THE MANAGEMENT OF AGEING RELATED DEGENERATIVE SYMPTOMS

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INTRODUCTION

Ageing related conditions consist of degenerative, inflammatory & atrophy/wasting illness & mood disorders amongst ageing male & female.

The first line treatment for these conditions are symptomatic control drugs. However, there is a growing number of patients who are prescribed multiple classes & aggressive dose of symptomatic control drugs for their ageing conditions but failed to attain sustainable long term improvements.

These patients are then prescribed combination therapy where symptomatic control drugs will be used concommitantly with hormonal drugs for increased positive outcomes.

Hormonal durgs commonly prescribed in the United States are :

- Testosterone depots
- Conjugated estradiol / medroxy progesterone acetate
- Recombinant human growth hormones

Despite the effectiveness of the combined therapy approach in providing rapid & significant short term improvements in ageing related complaints, however patients prefer a more practical, sustainable & less vigorous approach in the long run.

OBJECTIVES

Okinawa Food Beverage Powder (OFBP) is a botanical food powder that contains subteranean underground root vegetations which are reputed to impart youthful qualities & ageing related symptoms in the Japanese Okinawan population. However their mechanism of action is not well understood for the past 100 years. The objective of this pilot study is :

- To evaluate the safety, efficacy & practicality of Okinawa Food Beverage Powder (OFBP) in :
  1: managing ageing related degenerative conditions
  2: imparting positive youthful physical & mental attributes
- To compare the safety, efficacy & practicality of other viable alternatives such as IGF-1 sublingual sprays, synthetic estrogens, testosterone depots injections & HGH injections.
- To evaluate the efficacy of combining OFBP with additional dietary proteins & healthy fats in producing the most accelerated & significant positive outcomes in patients.

DESIGNS

Pilot Study Submission No
SOMA PILO94622 – 2006

Study Duration
1 year prospective, multicenter, open-label, non-randomized study.

Study Commencement
1st June 2006

Study Completion Date
30th June 2007

Date of Report
25h July 2007

No. of Participants
45 patients

Time Points of Assessment

T0 – Baseline Established
T1 – 4 weeks after entry;
T2 – 8 weeks after entry;
T3 – 12 weeks after entry & Safety Studies
T4 – 16 weeks after entry;
T5 – 20 weeks after entry;
T6 – 24 weeks after entry & Safety Studies
T7 – 28 weeks after entry;
T8 – 32 weeks after entry;
T9 – 48 weeks after entry & Safety Studies

FINISHED PRODUCT

Okinawa Food Beverage Powder (OFBP)

ACTIVE INGREDIENTS

Fermented Botanicals

1 :	Fermented Soy Lecithin	2,000 mg
2 :	Fermented White Potato	645 mg
3 :	Fermented Sweet Potato	640 mg
4 :	Honeydew Melon	290 mg
5 :	Fermented Asparagus	270 mg
6 :	Fermented Potato Root	265 mg
7 :	Fermented Brown Rice	260 mg
8 :	Fermented Soy Paste	260 mg

Sprouted Botanicals

1 :	Sprouted Soy Beans	260 mg

INACTIVE INGREDIENTS

1 :	Natural Flavoring	90 mg
2 :	Natural Stevia	10 mg
3 :	Tricalcium phosphate	10 mg

PROCEDURES

Patient Eligibility

Patients eligible for study include those who are able to complete all questionnaires & forms and to those who have no comorbidities dominating at the moment of the study. The project staff in the pilot study will review the patients medical records to determine their eligibility and will enter eligible patients' medical records into the patient - recruitment database.

Patient Education

The project staff in the pilot study will then approach patients, explain the study, ask them to participate & acquire their signed informed consent(s). A 30 day supply of the product OFBP will be provided upon consent. Patients will return to their respective home states (East Coast & West Coast of the United States). They will continue to maintain regular appointments with their existing family physicians & continue with all existing allopathic medication protocol which has been prescribed by their physicians while concommitantly consuming OFBP following our protocol.

Data Collection Procedure

Data will be collected once every 4 weeks for 12 months
Safety studies are conducted once every 3 months
Patients will complete questionnaires (QF06) & (QF07) at each time point (T).

Establishing Baseline Levels

Upon admission into the study, each patient must submit blood samples for laboratory testing to establish their baseline serum levels.

FORMS & QUESTIONNAIRES

Initial Lab Test
To Establish Baseline

Form QF05
Comorbidity Checklist
To be filled by our appointed physician at T0 (baseline) for each patient

Form QF06 Questionnaire
Quality of Life (QOL)
To be filled by patient at each time point (T)

Form QF07 Questionnaire
Symptom Assessment (MDASI)
To be filled by patient at each time point (T)

Checklist T0
Patient Health Conditions, Treatment & Demographics Data
To be filled by our appointed physician at T0 (baseline) for each patient.

Checklists T1-T8: Patient Health Conditions & Treatment information
To be filled by our appointed physician at T1-T8 for each patient

NUMBER OF SUBJECTS :
45 participants

TARGET POPULATION & AGE

Female & male patients experiencing
1: Ageing related conditions & symptoms
2: Premature & Rapid ageing

Female	***No of participants***
Age 40 - 54	22
Male	***No of participants***
Age 40 - 54	23
Total	45

ASSESSMENTS

Efficacy of OFBP is evaluated by

1: **% Improvement in Serum Test Markers :**
- Insulin Like Growth Factor-1 IGF-1
- Epidermal Growth Factor EGF
- Nerve Growth Factor NGF
- Insulin Like Growth Factor Binding Protein IGFBP3

2: **% Improvement in Quality of Life (QOL) Questionnaire**

In Social Life & Interaction
In Mood & Cognitive Functions
In Anxiety & Depression
In Energy Levels & Sexual Function

Test Markers & Regulatory/Safety Markers

Historically, the most practical test marker of ageing is in the measurement of insulin like growth factor (IGF-1). It is generally regarded by clinical practitioners that higher IGF-1 levels will signal increased levels of cell rejuvenation leading to greater positive outcomes for patients. However in actual clinical settings, it was observed that the historical assumptions & past hypothesis may be wrong. It was previously observed in past clinical practices that an elevated IGF-1 did not consistently resulted in positive outcomes for patients.

Apart from IGF-1 there are 2 other types of growth factors (EGF & NGF) whose levels must also be elevated to produce significant positive outcomes that can be identified by patients.

Primary Test Markers

- Insulin Like Growth Factor-1 IGF-1

Secondary Test Markers

- Epidermal Growth Factor EGF
- Nerve Growth Factor NGF

Regulatory & Safety Test Marker

- Insulin Like Growth Factor (Binding Protein) IGFBP3

IGF-1 encourages healthy cell proliferation & promotes new growth of cells resulting in youthful attributes & improvements in most ageing related symptoms.

However an excessive, unregulated & unopposed levels of IGF-1 can cause excessive cell proliferation activity which is not desirable. Fortunately, the human physiology possess a reliable safety & regulatory mechanism to prevent this occurance.

Human hepatic cells produce a type of binding protein termed as IGF1BP to bind strongly to 80% of IGF-1 to regulate their proliferative activity, in the same manner that hepatic cells also produce another binding protein termed as SHBG to bind 80% of testosterone to similarly regulate their proliferative activity.

Therefore, binding proteins are the most reliable safety & regulatory mechanism to control all proliferative & stimulatory types of growth factors and hormones such as IGF-1, Human Growth Hormones, Testosterone & Estrogen.

In normal & healthy subjects, levels of IGF-1 & IGF1BP will rise at almost the same pace during any ageing management or anti-ageing therapies. This ensures that the increased IGF-1 levels do not exert excessive proliferative effects on cells.

However, this highly reliable and consistent safety mechanism can sometimes be dysregulated by externally administering products containing high potency hormones or IGF-1 such as HGH injections or IGF-1 sublingual sprays. These products can result in an instantaneous, rapid and excessive rise in IGF-1 which quickly overwhelms the production IGF1BP. This leads to an undesirable situation where there is massive quantities of IGF-1 with very low levels of protective IGF1BP binding protein.

This study seeks to evaluate the safety of these IGF-1 & HGH containing products.

Test Design

45 participants aged 40 to 54 were divided into the following groups :

Group 1	Control Group	10 subjects
Group 2	OFBP	10 subjects
Group 3	OFBP with additional 2 tbsp protein & 2 tbsp healthy fats	10 subjects
Group 4	IGF-1 sublingual spray @ 3 servings per day	10 subjects
Group 5	Recombinant Injectable HGH @ 0.01mg/kg/day	5 subjects

Group 1: Control Group

All 10 participants are not consuming OFBP, IGF-1 sprays or HGH Injections.

3 female participants above age 50 in control group are currently receiving HRT

- Synthetic conjugated estradiol / medroxy progesterone - 1 tablet / day

2 male participants above age 50 in control group are receiving HRT

- Synthetic testosterone depot - 1 injection every 7 days

No dietary changes or other dietary supplements allowed

Group 2: Somaplus™ OFBP

All 10 participants were prescribed only OFBP

5 males — Loading Phase : 1 serving before bed & upon awakening in morning (30 days)
Maintenance Dose : 1 serving (5 days on/2 days off, repeat cycle)

5 females — Same as above

No dietary changes or other dietary supplements allowed

Group 3: Somaplus™ OFBP with Increased protein & Healthy Fats

All 10 participants were prescribed OFBP with

OFBP (same as Group 2)

additional 20 grams protein : 2 heaping tbsp/day away from OFBP**
additional 30 grams healthy fats : 2 tbsp/day away from OFBP**

No other dietary supplements allowed.

Important Note To Group 3 Participants
OFBP must be consumed on an empty stomach away from all food and snacks.
Therefore, the additional protein & fats above should not be consumed at the same timing with OBFP.

OFBP Dispensing Instructions
45 minutes before any food or snacks or
3 hours after any foods or snacks
No other dietary supplements are allowed

Group 4: IGF-1sublingual spray @ 3 servings per day

All 10 participants were issued a 30 ml liquid spray bottle with attached mist spray pump containing liquified deer antler extract.
No dietary changes or other dietary supplements allowed

Manufacturer's label claims on bottle
Deer antler liquid contains IGF-1.
3,000 ng of IGF-1 / bottle or 50 ng of IGF-1/serving
Serving Size : 3 sprays / serving.
3 sprays under the tongue for 3 times a day.
Retain liquid for 10 minutes then swallow.
Product is absorbed sublingually via the oral buccal mucosa.
It does not rely on GI tract absorption.
Therefore, product can be administered sublingually anytime with or without food.

Group 5: Recombinant Injectable HGH @ 0.01mg/kg/day

All 5 participants purchased recombinant HGH injections from their respective physicians

2 males — 1 self administered subcutaneous HGH injection daily
3 females — Same as above

No dietary changes or other dietary supplements allowed.

Control

Mean Serum Levels												
Test	**Reference Range**	**Baseline**	**T1**	**T2**	**T3**	**T4**	**T5**	**T6**	**T7**	**T8**	**T9**	**Variance %**
IGF-1	90-360 ng/mL	135.2	136.3	133.0	133.8	134.7	134.0	132.00	133.4	130.1	132.6	– 1.9%
EGF	700-1700 pg/mL	725.7	730.5	723.7	724.3	720.3	730.8	733.3	735.5	734.0	735.9	+ 1.4%
NGF	11.06–41.74 pg/mL	15.2	15.2	15.5	15.8	15.7	15.7	15.7	15.7	15.8	15.7	0%
IGFBP3	3.3–6.8 mcg/mL	2.9	3.0	2.8	2.8	3.0	3.0	2.8	2.8	2.7	2.8	– 3.4%

Group 2: Somaplus™ OFBP

Mean Serum Levels												
Test	**Reference Range**	**Baseline**	**T1**	**T2**	**T3**	**T4**	**T5**	**T6**	**T7**	**T8**	**T9**	**Variance %**
IGF-1	90-360 ng/mL	143.1	209.09	230.5	246.1	267.4	270.4	288.9	295.5	310.1	317.4	+ 121.8%
EGF	700-1700 pg/mL	760.6	784.9	798.0	810.6	845.0	855.3	880.3	901.5	910.6	913.1	+ 20.0%
NGF	11.06–41.74 pg/mL	16.6	18.4	18.4	18.8	19.0	24.3	26.4	26.9	33.3	33.5	+ 101.8%
IGFBP3	3.3–6.8 mcg/mL	3.1	4.6	4.7	4.9	5.1	5.3	5.6	5.7	5.8	6.3	+ 103.2%

Group 3: Somaplus™ OFBP + Protein

Mean Serum Levels												
Test	**Reference Range**	**Baseline**	**T1**	**T2**	**T3**	**T4**	**T5**	**T6**	**T7**	**T8**	**T9**	**Variance %**
IGF-1	90-360 ng/mL	138.2	245.5	266.0	278.5	302.0	310.6	318.0	320.3	333.5	337.0	+ 143.8%
EGF	700-1700 pg/mL	734.4	764.2	785.5	803.3	845.0	861.6	696.0	917.2	929.4	943.4	+ 28.5%
NGF	11.06–41.74 pg/mL	13.7	16.9	20.4	24.6	27.9	31.5	33.3	36.1	37.2	38.1	+ 178.1%
IGFBP3	3.3–6.8 mcg/mL	3.1	4.9	5.1	5.5	5.7	5.8	5.9	5.9	6.1	6.7	+ 116.1%

Group 4: IGF-1 Sublingual Spray

Mean Serum Levels												
Test	**Reference Range**	**Baseline**	**T1**	**T2**	**T3**	**T4**	**T5**	**T6**	**T7**	**T8**	**T9**	**Variance %**
IGF-1	90-360 ng/mL	150.5	265.4	281.0	317.4	330.1	367.2	400.3	425.1	430.3	431.7	+ 186.8%
EGF	700-1700 pg/mL	730.0	732.0	732.2	729.1	730.5	730.1	731.0	729.9	730.3	731.1	+ 0.2%
NGF	11.06–41.74 pg/mL	14.9	16.2	16.3	15.4	15.1	15.2	16.5	17.3	16.9	16.5	+ 10.7%
IGFBP3	3.3–6.8 mcg/mL	3.8	5.0	5.6	5.9	6.8	6.7	6.3	6.1	6.0	5.5	+ 44.7%

Group 5: Human Growth Hormone (HGH) Injection

Mean Serum Levels												
Test	**Reference Range**	**Baseline**	**T1**	**T2**	**T3**	**T4**	**T5**	**T6**	**T7**	**T8**	**T9**	**Variance %**
IGF-1	90-360 ng/mL	125.2	334.1	380.6	378.3	375.2	380.0	382.2	390.4	388.9	383.1	+ 206.0%
EGF	700-1700 pg/mL	676.4	875.5	1230.0	1456.6	1780.1	1905.0	2015.5	2015.0	2016.1	2018.0	+ 198.3%
NGF	11.06–41.74 pg/mL	11.1	32.5	55.8	65.1	77.1	76.1	75.0	75.1	74.8	73.2	+ 559.5%
IGFBP3	3.3–6.8 mcg/mL	4.0	6.1	6.8	6.9	7.5	6.5	6.2	6.1	5.8	5.7	+ 42.5%

OBSERVATIONS & DISCUSSIONS

Control Group

All 10 participants (aged 40-54) including 5 HRT users did not experience any improvements in IGF-1, EGF, NGF or IGF-BP3.

Females in control group

The 3 females on HRT in the control group reported that female HRT medications were highly successful in providing significant improvements for symptoms (hot flushes, night sweats, extreme dryness of skin, irritability, fatigue & mild depression).
All 3 female HRT users reported no noticeable improvements in managing their ageing related symptoms or youthful attributes.

Males in control group

The 2 males on HRT in the control group currently on testosterone depot injections reported improved muscle strength, endurance, stamina, motivation & reduced muscle wasting (atrophy).

Adverse side effects were uncontrolled aggression, elevated LDL blood pressure & hepatic enzymes while significantly lowering protective HDL levels after 3 months on testosterone injections.

Male patients reported that HRT for men improve their ageing related degenerative symptoms but can adversely affect long term health.

Therefore, a more suitable product will be required for targeting long term, ageing related degenerative symptoms in both male & female.

Group 2

122% increase in IGF-1 in 12 months within permissible limits is balanced by a 102% increase in IGFBP3 binding protein. In the human physiology, an increase in serum IGF-1 is always balanced closely by an approximate increase in serum IGF1BP binding protein. IGF1BP deactives 80% of IGF-1. This binding is normal for regulating the strong stimulatory & proliferative effects of IGF-1.

Therefore, IGF1BP is antagonistic to IGF-1. This "cancelling out action" by IGF1BP serves as a necessary safety and balancing mechanism as IGF-1 is proliferative & IGFBP3 is anti-proliferative. There was also marked improvements in EGF & NGF levels within permissible limits.

Patients' questionnaires on quality of life (QOL) scores seems to correlate with the lab assay results. They reported a deep sense of rejuvenation upon awakening in the morning, absence of fatigue or sleepiness throughout the day, improved cognition, better mood, improved muscular strength & sleep quality.

Group 3

144% increase in IGF-1 in 12 months is balanced by a 116% increase in IGFBP3 binding proteins to prevent IGF-1's excessive stimulatory effects. IGF-1, EGF & NGF showed highly significant improvements within permissible limits.

Consuming OFBP with additional protein & healthy fats produced the most impressive lab assay results and in the treatment of ageing related degenerative symptoms as expressed in the QOL Quality of Life Questionnaire.

Group 4

186% increase in IGF- in 12 months beyond the maximum permissible limit created excessive and highly stimulatory IGF-1 which is not sufficiently opposed by binding proteins. A very limited 45% increase in IGFBP3 binding protein was observed in this study.

External (exogenous) administration of IGF-1 via sublingual spray also failed to increase EGF & NGF levels.

Results of lab assays correlate with patients feedback that the impressive IGF-1 values deer anther products commonly produced failed to translate into long term positive clinical benefits. Correlation between lab assay results and questionnaire feedback indicates clearly that an increase solely in IGF-1 level without a corresponding increase in other "tissue specific" growth factors such as EGF & NGF will not provide significant positive outcomes for patients in terms of management of ageing related degenerative symptoms. Despite this, deer antler is a good adaptogen for stress management.

Deer antler has very high TEF rating (Thermic Effect of Food). When deer antler is consumed and metabolised, it releases an extremely high quantity of heat energy. 5 patients in Group 4 experienced excessive perspiration, itchy skin rashes, dry cracking lips, sore throats, pimple/acne outbreaks, painful mouth ulcers (canker sores) & eczema flare-ups.

Group 5

206% increase in IGF-1 in 12 months beyond the maximum permissible safe limit created the largest excess in highly stimulatory & proliferative IGF which is not opposed by binding protein. A very limited 42% increase in IGFBP3 binding protein was observed in this study.

External (exogenous) administration of Human Growth Horrmone via self administered daily injections also excessively increased EGF & NGF beyond their maximum permissible safe limits.

Questionnaire feedback indicated that most patients on human growth hormones had water retention, stiff joints, with frequent headaches & neckaches. Patients had some positive outcomes in managing ageing related symptoms however the discomfort caused by the treatment nullified its benefits.

All 5 patients stopped HGH treatment after 12 months as the positive benefits received does not correlate with its health risks, extremely high cost & difficult compliance.

SUMMARY

Somaplus™ OFBP

OFBP is the safest & most effective age management food with no adverse side effects or health risks as it does not contain hormones or IGF-1. It stimulates endogenous internal production of healthy levels of IGF-1, EGF, NGF & IGF1BP with fermented vegetations. Therefore its rejuvenative effects on cells is both safe & tightly regulated by corresponding levels of IGF1BP binding proteins.

OFBP does not contain any hormones or growth factors and therefore long term use does not cause a shutdown of internal endogenous hormonal production. Hence, patients will not develop a dependence on OFBP. It is non-addictive.

Increased consumption of protein and healthy fats is clinically proven to improve the effectiveness of OFBP.

IGF-1 sublingual sprays

The raw material are usually deer antler liquid or colostrum liquid containing very low trace levels of naturally occurring IGF-1. Then the liquid is fortified with massive quantities of synthetically synthesized IGF-1 from China. This creates a product containing abnormally high levels of the highly proliferative IGF-1. This type of product is clinically proven to rapidly push IGF-1 levels in all 10 participants beyond their safe upper limits.

Therefore, usage of this product creates abnormal supra-physiological levels of IGF-1 which is unopposed by regulatory IGF1BP binding protein. This type of scenario can result in excessive cell stimulation & proliferation which may lead to tumor formation. It can constitute a "dose-dependent" health risks.

Its abnormally high IGF-1 content is not naturally occurring in any deer antlers or colostrum and can shutdown internal endogenous production of hormones via 1 subject on testosterone injection had high creatinine, the negative feedback loop. This leads to long term dependence & addiction. Upon cessation of use after 12 months, 8 participants experienced IGF-1 withdrawal symptoms such chronic fatique, adrenal exhaustion, irritability & severe mood swings OFBP users do not experience any of these withdrawal symptoms as it does not contain IGF-1.

Testosterone Injections

HGH Injections

Both product categories involve the use of synthetically made hormones whose unique & patented carbon structure & side chains do not exist in humans or animals.

The "patentable" differences in their carbon structure & side chains caused side effects such as water retention, aggression, adverse hepatic, hypertension & lowering of protective HDL levels.

Comprehensive Hepatic & Renal Panel For All Groups

Safety Studies – 12 weeks after entry

In Control Group	10 pass	
In Group 2	10 pass	
In Group 3	10 pass	
In Group 4	10 pass	
In Group 5	5 pass	

Safety Studies – 24 weeks after entry

In Control Group	10 pass	
In Group 2	10 pass	
In Group 3	10 pass	
In Group 4	7 pass	3 subjects on IGF-1 spray had abnormal liver enzymes
In Group 5	5 pass	

Safety Studies – 48 weeks after entry

In Control Group	8 pass	2 subjects on testosterone injection had high creatinine
In Group 2	10 pass	
In Group 3	10 pass	
In Group 4	10 pass	
In Group 5	3 pass	2 subjects on HGH injections had abnormal liver enzymes