

Study Identification

Unique Protocol ID: Genepro Gen 2

Brief Title: Absorption Comparison on Equivalency Value of Genepro Gen2

Official Title: Genepro Gen2 Equivalency Study as Compared to Whey Isolate (1 Tablespoon of Genepro Gen2 and 30g Whey Isolate.

Secondary IDs:

Study Status

Record Verification: November 2016

Overall Status: Completed

Study Start: June 2016

Primary Completion: September 2016 [Actual]

Study Completion: September 2016 [Actual]

Sponsor/Collaborators

Sponsor: Musclegen Research, Inc.

Responsible Party: Sponsor

Collaborators:

Oversight

FDA Regulated?: No

IND/IDE Protocol?: No

Review Board: Approval Status: Approved
Approval Number: ARP119710
Board Name: MedFit Rx
Board Affiliation: Independent
Phone: 984-200-2964

Email: info@medfitrx.net

Data Monitoring?: Yes

Plan to Share IPD?: Yes

10 subjects will be administered genepro for the first 6 weeks of the study and whey protein the last 6 week. The other 10 subjects will be administered whey protein for the first 6 weeks of the study and Genepro Gen2 for the last 6 weeks. Weekly blood draws will be taken from each subject to analyze blood protein levels.

Oversight Authorities: United States: Institutional Review Board

Study Description

Brief Summary: Genepro Gen2 Absorption and Protein Value Clinical Trial.

Detailed Description: Objective: To prove the absorbability and usability of Genepro Gen2 Protein and compared to whey isolate. This study is intended to show the equivalent value of Genepro Gen2 as compared to whey protein isolate (1 tablespoon Genepro Gen2 compared to 30g serving of whey isolate)

Parameters: This study encompasses a 12-week program that follows 20 gastric bypass patients that have undergone weight loss surgery. We took a baseline blood analysis prior to the start of the study and subsequently we took weekly blood work to chart and register the findings. For this study we will only be doing the weekly analysis on blood protein levels by utilizing Spectrophotometry. The target blood protein range is 6.1-8.7 g/dL this test is administered while fasting.

Participants: 20 Post Op Gastric Bypass patients. 10 men, 10 women. All participants were between the ages of 30-46 years of age. All participants have been post operation from their weight loss surgery for a minimum of 3 months prior to the start of the study and no longer than 12 months at the start of the study.

Gathering Results: 10 subjects will receive Genepro Gen 2 protein (1 tablespoon serving) for the first 6 weeks of the study and for the last six weeks, they will receive 30g of Whey protein. In conjunction the other group of 10 subjects will receive 30g whey protein the first 6 weeks of the study and Genepro Gen2 protein the final six weeks. Weekly blood analysis will determine blood protein levels.

Diet: Diet guidelines limit the calories you consume while providing you with balanced meals to help prevent nutritional deficiencies and preserve your muscle tissue. Each patient tolerates suggested foods differently.

Daily calories should be between 600 to 700 for the duration of this study. Each subject is to follow a diet low in calories, fats and sweets. The goal for each subject is to consume a minimum of 65 to 75 grams of protein a day. High protein foods include eggs, meats, fish, seafood, tuna, poultry, tofu, milk, soy, cottage cheese, and yogurt. 30g of each daily intake of protein will be provided by a powdered protein supplement. Each subject will utilize a 30g serving of whey isolate for 6 weeks of their study and for the other 6 weeks the subject will use a single serving (1tablespoon) of Genepro Gen2 Protein.

Subject were given the following eating guidelines:

- Eat slowly and chew small bites of food thoroughly.
- Avoid rice, bread, raw vegetables, fresh fruits, and meats that are not easily chewed such as pork and steak. Ground meats are usually better tolerated.

- With soft and solid foods, take only three bites at one sitting, then wait a minimum of 20 minutes before eating more.
- Eat balanced meals with small portions.
- Avoid the use of drinking straws and carbonated beverages, chewing gum and ice because they can introduce too much air into your pouch and cause discomfort.
- Avoid sugar, sugar-containing foods and beverages, concentrated sweets, and fruit juices. Alcoholic beverages will have a more profound effect and should be avoided or consumed with caution.

Exercise: Each subject is asked to exercise for 30 to 45 minutes a day, with cardio or aerobic activity three to five times a week. Initially, we recommend walking five minutes in the morning and five minutes in the late afternoon. As tolerated you should increase these intervals by five minutes until you are walking at least 15 minutes twice per day.

Conditions

Conditions: Analysis, Event History
Absorption; Disorder, Protein

Keywords:

Study Design

Study Type: Interventional

Primary Purpose: Screening

Study Phase: Phase 4

Intervention Model: Crossover Assignment

Number of Arms: 2

Masking: Open Label

Allocation: Non-Randomized

Endpoint Classification: Bio-equivalence Study

Enrollment: 20 [Actual]

Arms and Interventions

Arms	Assigned Interventions
<p>Active Comparator: Genepro Gen2 Protein 1 tablespoon Serving of Genepro Gen2 Protein daily will be used in each subject.</p> <p>Intervention: Weekly blood draws will determine the effect on blood protein levels.</p>	<p>Dietary Supplement: Genepro Protein weekly blood draws to measure blood protein levels</p> <p>Other Names:</p> <ul style="list-style-type: none"> • Genepro

Arms	Assigned Interventions
<p>Active Comparator: Whey Protein Isolate 30g Serving of Whey Isolate Protein will be used daily in each subject.</p> <p>Intervention: Weekly blood draws will determine the effect on blood protein levels.</p>	<p>Dietary Supplement: Whey Protein weekly blood draws to measure blood protein levels</p> <p>Other Names:</p> <ul style="list-style-type: none"> • Whey Protein Isolate

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age: 30 Years

Maximum Age: 46 Years

Gender: Both

Accepts Healthy Volunteers?: Yes

- Criteria:
- 20 Post Op Gastric Bypass patients.
 - 10 men,
 - 10 women.
 - Minimum age 30
 - Maximum age 46
 - All participants have been post operation from their weight loss surgery for a minimum of 3 months prior to the start of the study and no longer than 12 months at the start of the study.

Exclusion Criteria:

- Any digestive distress disorder (IBS, Crohns, etc).

Contacts/Locations

Study Officials: David Michael, RN
Study Principal Investigator
MuscleGen Research, Inc.

Brian M Parks, PHD
Study Director
MedFit Rx, Inc.

Tony R Parks, BS
Study Principal Investigator

Locations:

References

Citations:

Links:

Study Data/Documents:

Study Results

Participant Flow

Recruitment Details	Open call for bariatric patients via social media and direct mail marketing.
Pre-Assignment Details	NONE

Reporting Groups

	Description
Genepro Gen2 Protein Then Whey Protein	1 tablespoon Serving of Genepro Gen2 Protein daily will be used in each subject. 30g Serving of Whey Isolate Protein will be used daily in each subject.
Whey Protein Isolate Then Genepro Gen2 Protein	30g Serving of Whey Isolate Protein will be used daily in each subject. 1 tablespoon Serving of Genepro Gen2 Protein daily will be used in each subject.

Overall Study

	Genepro Gen2 Protein Then Whey Protein	Whey Protein Isolate Then Genepro Gen2 Protein
Started	10 ^[1]	10 ^[1]
Completed	10 ^[2]	10 ^[2]
Not Completed	0	0

[1] 10 Participants

[2] completed with the same initial 10 participants

Baseline Characteristics

Baseline Analysis Population Description

20 Post Op Gastric Bypass patients. 10 men, 10 women. All participants were between the ages of 30-46 years of age. All participants have been post operation from their weight loss surgery for a minimum of 3 months prior to the start of the study and no longer than 12 months at the start of the study.

Reporting Groups

	Description
All Participants	All participants were given a baseline blood analysis

Baseline Measures

		All Participants
Overall Number of Participants		20
Age, Categorical	Measure Type: Participants Unit of measure: participants Number Analyzed	20 participants
	<=18 years	0 0%
	Between 18 and 65 years	20 100%
	>=65 years	0 0%
Age, Continuous	Mean (Standard Deviation) Unit of measure: years Number Analyzed	20 participants
		39 (1)
Gender, Male/Female	Measure Type: Participants Unit of measure: participants Number Analyzed	20 participants
	Female	10 50%

		All Participants
	Male	10 50%
Region of Enrollment	Measure Type: Unit of measure: Number Analyzed	20 participants
United States		20
Protein blood levels ^[1]	Mean (Standard Deviation) Unit of measure: g/dl	
Genepro Gen2 first	Number Analyzed	10 participants
		7.1 (.4)
Whey Isolate first	Number Analyzed	10 participants
		6.9 (.4)
All Participants	Number Analyzed	20 participants
		7.0 (.4)
		[1] Measure Analysis Population Description: Participants assessed separately for each sequence.

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Weekly Blood Draws to Measure Blood Protein Levels
Measure Description	Each week the 20 participants will have blood drawn to measure their blood protein levels. Each participant was required to give blood weekly to determine the blood protein levels. The results show the average over each six week period of testing for each row. Each participant was examined to see if they achieved the average

	range as set fourth by the dieticians of greater than 6.1 and less than 8.7 within a 10% variable as acceptable. 10 Participants will be given Genepro Gen2 for the first six weeks of the study and whey protein for the final 6. 10 Participants will be given whey protein for the first six weeks of the study and Genepro Gen2 for the final 6. These measurements will read in g/dl
Time Frame	6 weeks per intervention
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
Genepro Gen2 Protein	1 tablespoon Serving of Genepro Gen2 Protein daily will be used in each subject. Intervention: Weekly blood draws will determine the effect on blood protein levels. Genepro Protein: weekly blood draws to measure blood protein levels
Whey Protein Isolate	30g Serving of Whey Isolate Protein will be used daily in each subject. Intervention: Weekly blood draws will determine the effect on blood protein levels. Whey Protein: weekly blood draws to measure blood protein levels

Measured Values

	Genepro Gen2 Protein	Whey Protein Isolate
Number of Participants Analyzed	20	20
Weekly Blood Draws to Measure Blood Protein Levels	Mean (Standard Deviation) Unit of measure: grams per deciliter	
Female Age 37	7.23 (.4)	6.86 (.4)
Male Age 34	7.43 (.7)	7.21 (.3)
Male Age 30	7.1 (.5)	7.28 (.2)
Female Age 32	7.16 (.3)	6.95 (.1)
Female Age 40	7.2 (.3)	6.86 (.2)

	Genepro Gen2 Protein	Whey Protein Isolate
Male Age 40	7.11 (.8)	6.08 (1.1)
Male Age 34	7.05 (.6)	6.95 (.5)
Female Age 34	6.6 (.2)	6.46 (.3)
Female Age 37	6.55 (.2)	6.65 (.2)
Male Age 39	7.18 (1.1)	6.88 (.3)
Female Age 30	6.81 (.5)	6.58 (.2)
Male Age 46	6.81 (.5)	6.58 (.2)
Female Age 39	6.76 (.3)	6.03 (.5)
Male Age 36	6.81 (.5)	6.48 (.2)
Female Age 32	6.88 (.6)	6.26 (.4)
Male Age 38	7.18 (.5)	6.83 (.8)
Female Age 36	6.73 (.9)	6.31 (.4)
Male Age 34	7.13 (.4)	7 (.4)
Female Age 36	6.13 (.8)	6 (.8)
Male Age 41	7 (.5)	6.95 (.3)

Reported Adverse Events

Time Frame	[Not specified]
Additional Description	No adverse events were monitored

Reporting Groups

	Description
Genepro Gen2 Protein	1 tablespoon Serving of Genepro Gen2 Protein daily will be used in each subject. Intervention: Weekly blood draws will determine the effect on blood protein levels. Genepro Protein: weekly blood draws to measure blood protein levels
Whey Protein Isolate	30g Serving of Whey Isolate Protein will be used daily in each subject. Intervention: Weekly blood draws will determine the effect on blood protein levels. Whey Protein: weekly blood draws to measure blood protein levels

Serious Adverse Events

	Genepro Gen2 Protein	Whey Protein Isolate
	Affected/At Risk (%)	Affected/At Risk (%)
Total	0/0	0/0

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 0%

	Genepro Gen2 Protein	Whey Protein Isolate
	Affected/At Risk (%)	Affected/At Risk (%)
Total	0/0	0/0

Limitations and Caveats

[Not specified]

More Information

Certain Agreements:

Principal Investigators are NOT employed by the organization sponsoring the study.

There IS an agreement between the Principal Investigator and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

Results Point of Contact:

Name/Official Title: David Michael

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