

Improvements in muscle recovery and delayed onset muscle soreness (DOMS) reduction after eccentric exercise with the BounceBack™ product: a randomised, double-blind, two-way crossover, placebo-controlled, pilot study

Submission date 17/09/2008	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 09/10/2008	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 09/10/2008	Condition category Musculoskeletal Diseases	☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
MANN1001

Study information

Scientific Title

Study objectives

The current study was designed to induce delayed onset muscle soreness (DOMS) in healthy untrained volunteers, assess the level of DOMS through functional and biochemical methods, and determine if the BounceBack™ product is superior to placebo in accelerating recovery from this condition.

Ethics approval required

Old ethics approval format

Ethics approval(s)

This study was approved by Copernicus Group IRB on 11/02/2007.

Study design

Randomised, double-blind, placebo-controlled, two-way crossover, pilot trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Delayed onset muscle soreness (DOMS)

Interventions

The test product is BounceBack™, which contains enzymes, curcumin, vitamin C, avocado, soy extract and resveratrol.

Dosage: BounceBack™ (oral) 1000 mg/day

Schedule of interventions:

Thirty days of consumption of the test product or placebo, followed by exercise on Day 31 and post-exercise evaluations on Day 32, 33 and 34. After a two-week washout period, the intervention was repeated in a crossover design.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

BounceBack™

Primary outcome(s)

Pain (Visual Analogue Scale [VAS]) and tenderness, assessed at baseline (pre-exercise), and then at 6, 24, 48 and 72 hours post-exercise.

Key secondary outcome(s)

The following were assessed at baseline (pre-exercise), and then at 6, 24, 48 and 72 hours post-exercise:

1. Inflammation
2. Muscle damage

Completion date

30/04/2008

Eligibility

Key inclusion criteria

1. Both males and females, age ≥ 18 and ≤ 45 at screening
2. Body mass index (BMI) $> 18 \text{ kg/m}^2$ and $\leq 30 \text{ kg/m}^2$ at screening
3. Recreationally active but non-resistance trained for the preceding 3 months
4. Agree to dietary modifications for the day prior to each visit
5. Subject agrees to all study visits
6. Must agree to use appropriate birth control methods during the active study

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Non-compliance during the screening phase of the study
2. Weight loss of > 10 pounds in the last 6 months
3. Pregnant or lactating
4. Currently attempting to become pregnant
5. Use of medications or supplements promoting weight gain (steroids, high-protein supplements)
6. Daily use of acid blocking medication. Must agree to withhold acid blocking medication while on study (Includes all prescription and over the counter acid blockers including PPIs, H2RAs, and calcium carbonate [Tums]).
7. Cigarette smoking
8. Abnormal physical examination
9. Subjects unable to understand or follow the study protocol

10. Subjects participating or participated in another clinical trial during the 1 month prior to screening
11. Subjects with active eating disorder including anorexia nervosa, bulimia, restrained eating, and/or obsessive compulsive eating disorders (Subjects will be screened with a standardised eating disorder questionnaire)
12. Subjects with known sensitivities to the ingredients in the product
13. Subjects with untreated significant depression or other psychiatric disease noted during the initial screening. Subjects with stable depression who are receiving medication and/or therapy may be included.
14. Subjects with active coronary artery disease, congestive heart failure, stroke, arrhythmia, or uncontrolled hypertension
15. Any liver, gallbladder or renal disease
16. Subjects with a history of seizure
17. Subjects with any cancer in the last 5 years (except skin cancer)
18. Subjects on anticoagulation therapy
19. Subjects with known alcohol abuse or recreational drug abuse
20. Subjects with chronic malabsorption
21. Subjects with a history of diverticulosis or diverticulitis
22. Subjects with inflammatory bowel disease (ulcerative colitis or Crohn's disease)
23. Subjects with a history of intestinal obstruction or those prone to intestinal obstruction
24. Subjects with short bowel syndrome
25. Subjects with a history of any surgery on their gastro-intestinal system
26. Subjects with a history of perforation of the stomach or intestines
27. Subjects with a history of pancreatitis, pancreatic insufficiency, pancreatic pseudocyst, carcinoma of the pancreas
28. Type I or type II diabetes
29. Subjects with any other endocrinologic disorders (including Cushing's syndrome and/or hypothyroidism)
30. Subjects with a history of lactic acidosis
31. Subjects with a history of symptomatic hypoglycemia
32. Subjects with brain and/or spinal cord injury
33. Subjects who have had diarrhoea in the month prior to the screening visit

Date of first enrolment

01/12/2007

Date of final enrolment

30/04/2008

Locations

Countries of recruitment

United States of America

Study participating centre

Medicus Research LLC

Northridge

United States of America

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Sponsor information

Organisation

Mannatech, Inc (USA)

ROR

<https://ror.org/031g1ba05>

Funder(s)

Funder type

Industry

Funder Name

Mannatech, Inc (USA)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration