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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

Registration date
09/10/2008

Overall study status
Completed

Last Edited
09/10/2008

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Jay Udani

Contact details
Medicus Research LLC
18250 Roscoe Blvd.
Suite 240
Northridge
United States of America
91325
+1 818 882 9442
jay.udani@medicusresearch.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

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

Secondary outcome measures
The following were assessed at baseline (pre-exercise), and then at 6, 24, 48 and 72 hours post-exercise:
1. Inflammation
2. Muscle damage

Overall study start date
01/12/2007

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 kg/m^2 and <=30 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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
10

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 psuedocyst, 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
91325

Sponsor information

Organisation
Mannatech, Inc (USA)

Sponsor details
600 S. Royal Lane
Suite 200
Coppell
United States of America
75019

Sponsor type
Industry

Website
http://www.mannatech.com

ROR
https://ror.org/031g1ba05

Funder(s)

Funder type
Industry

Funder Name
Mannatech, Inc (USA)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration