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A study to evaluate the efficacy and safety of Lipoxim Fire for weight management in overweight healthy women

Submission date
19/11/2020

Recruitment status
No longer recruiting

Registration date
04/12/2020

Overall study status
Completed

Last Edited
07/12/2020

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aim
Opportunities for physical activities are less and less while smartphone and technology pushes people to stay in their sofas and consume unhealthy foods and snacks. As result, overweight has grown fairly quickly over the past 14 years in countries, like France, Austria, Finland, Ireland regardless of sex, age, race, income or education level.
Physical inactivity causes a change in the gut microbiome. Imbalance in gut microbiota has been associated with many diseases, such as metabolic syndrome, type I and type II diabetes, cardiovascular diseases, allergy, eczema and autism.
Being overweight at midlife is associated with increased risk of dying. Researchers at the National Institutes of Health found that while obesity (defined as having a body mass index, or BMI, of 30 or more) among healthy non-smokers at age 50 is associated with two to three times the risk of death than that of healthy non-obese non¬smokers, being overweight (BMI of 25.0 to 29.9) but not obese also associated with an increased risk of dying.
Strategies aimed at preventing weight gain and obesity has not been successful to date. Follow up on longer periods confirm that maintaining weight loss is achieved only in a few individuals. Many options have been used for management of overweight and obesity. These include lifestyle and behavioural changes, and use of prescription and non-prescription drugs. Lifestyle and dieting approaches include restriction of caloric intake, and increased physical activity. These regimens are difficult to follow, may cause adverse effects and often result in regaining of lost weight when the intervention is stopped.
Prescription drugs that are currently available for obesity include serotoninergic agents (dexfenfluramine, fluoxetine), noradrenergic agents (sibutramine) and lipase inhibitors (orlistat). Although each of these drugs has been shown to be effective as to dietary modification and exercise, their benefits are limited by strong side effects that include cardiac valvular diseases, hypertension, seizures, sexual dysfunction, and irritable bowel syndrome.
Food extracts, herbs and botanicals have a potential in managing weight. Botanical dietary supplements often contain complex mixtures of plant chemicals that have harmonious interactions. Recently, the potential of many herbal ingredients against type II diabetes and cardiometabolic syndrome has been reviewed.
This research study was designed to test the impact of LIPOXIM FIRE ® (an extract of wakame

and curcumin), on weight loss in overweight women. The objective of the trial was to evaluate the effect of LIPOXIM FIRE on weight loss and body measurements over 30 days.

Who can participate?
Healthy female adult volunteers, between 25 to 60 years old (inclusive), with a body mass index (BMI) from 25.0 kg/m² to 29.9 kg/m²

What does the study involve?
Subjects were randomly assigned either LIPOXIM FIRE or dummy using simple randomization process to one of the two product intake groups:
Group 1: LIPOXIM FIRE
Group 2: Dummy

What are the possible benefits and risks of participating?
Benefits: Volunteering to participate in a weight loss clinical trial is beneficial to help with struggle of weight loss. Participants will receive regular and careful medical attention from a research team that includes doctors and other health professionals and gain access to new research treatments before they are widely available.
Risks: The study may require more time and attention than standard treatment would, including visits to the study site, more blood tests, and more procedures.

Where is the study run from?
INNOVATION LABO (Japan)

When is the study starting and how long is it expected to run for?
January 2018 to April 2020

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Yuki Ikeda, development@innovationlabo.com

Contact information

Type(s)
Scientific

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Protocol serial number
WF/NINAPHARM 18-7941A

Study information

Scientific Title
A prospective, randomized, double-blind, two-arm, parallel, placebo-controlled study to evaluate the efficacy and safety of Lipoxim Fire for weight management in overweight healthy women

Study objectives
Lipoxim Fire is more efficient than a placebo in inducing weight loss, fat mass loss and waist, hip and thigh circumference decrease

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 24/09/2018, Japanese Society of Anti-Aging Nutrition (5F Ginza, Chuo-ku, Tokyo 6-6-1, 104-0061, Japan; +81 3 3552 5277; coordinate@jaan.jp), ref: ILNP212018-S088

Primary study design
Interventional

Study design
Multicenter interventional double-blinded randomized controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Prevention of obesity in overweight women

Interventions
Product to be tested:
- Test group: LIPOXIM FIRE capsule
- Reference group: Placebo capsule
Amount : LIPOXIM FIRE, 2 capsules each before the 2 main meals, with a glass of water (200 ml)
Route of administration : Oral administration
Duration of administration: 30 days

Block randomization was used to divide potential patients into m blocks of size 2n, randomize each block such that n patients are allocated to A and n to B then choose the blocks randomly. This method ensures equal treatment allocation within each block if the complete block is used. Example: Two treatments of A, B and Block size of 2 x 2= 4 Possible treatment allocations within each block are (1) AABB, (2) BBAA, (3) ABAB, (4) BABA, (5) ABBA, (6) BAAB

Procedure for measuring waist circumference:
1. Waist circumference should be measured at a level midway between the lower rib margin and iliac crest with the measuring tape all around the body in horizontal position.
2. Subject were asked to stand erect, with feet together, breathe normally and abdomen relaxed. The reading of the measurement should be taken at the end of gentle exhaling.
3. Stand behind participant and locate the narrowest part of the torso
4. Subject were asked to lift arms while you place the measuring tape around the narrowest part of the torso.
5. Once tape is around the torso, ask participant to relax arms at their sides
6. Be sure tape is in a horizontal plane, evenly placed around the body and not catching on any clothing.
7. Measure waist circumference of subject and record in case report form
8. Record measurement to the nearest 0.1 cm.

Procedure for measuring hip circumference:
1. Hip circumference were measured as the maximal circumference over the buttocks
2. Subject were asked to stand erect with arms by sides and feet together. Weight should be evenly distributed on both feet
3. Squat or kneel down to the right side of the subject. Locate the level of maximum extension of the buttocks
4. Holding the zero end of the tape in your right hand, extend the measuring tape around the buttocks in a horizontal plane at this level.
5. Measure waist circumference of subject and record in case report form
6. Record measurement to the nearest 0.1 cm

Procedure for measuring thigh circumference:
1. Subject were asked to stand with his/her right leg just in front of the left leg, with weight on left leg
2. Squat or kneel down to the right of the participant. Holding the zero end of the tape in your right hand, place the measuring tape around the mid-thigh
3. Make sure the tape is positioned perpendicular to the long axis of the thigh, and not the floor
4. Measure waist circumference of subject and record in case report form
5. Record measurement to the nearest 0.1 cm

Intervention Type
Supplement

Primary outcome(s)
1. Body weight, body fat, lean mass, water mass and body mass index (BMI) at day 0, 15, 30, 45, 60 using InBody 720, (BioSpace Co. Ltd., Seoul, Korea)
2. Waist circumference, hip circumference, thigh circumference and waist/hip ratio at day 0, 15, 30, 45, 60
3. Self-evaluation questionnaire at day 30 and 60

Key secondary outcome(s)
Spontaneously reported and observed adverse events after first dose until end of product intake visit

Completion date
05/04/2020

Eligibility

Key inclusion criteria
1. Healthy non-smoker Asian or Caucasian female subjects between 25 to 60 years (inclusive) of age
2. Subject with BMI range of 25 - 29.9 kg/m² (both inclusive)
3. Subject using other therapies for weight management including physiotherapy/ occupational therapy agrees to discontinue these therapies
4. Subject agrees not to start any new therapies for weight loss during the course of the study
5. Females of child-bearing potential must agree to use an approved form of birth control and to have a negative pregnancy test result at the screening visit. Female subjects of non childbearing potential must be amenorrheic for at least 1 years or had a hysterectomy and/or bilateral oophorectomy
6. Willing to give written informed consent and willing to comply with the trial protocol
7. Ability to understand the risks/benefits of the protocol
8. Subject should be available for the duration of the study period (2 months)

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Total final enrolment
60

Key exclusion criteria
1. Subjects suffered from intractable obesity and had experienced recent unexplained weight loss or gain
2. Subject taking any over the counter weight loss agents, centrally acting appetite suppressants
3. Pathophysiologic/ genetic syndromes associated with obesity (Cushing’s syndrome, Turner’s syndrome, Prader Willi syndrome and thyroid disease)
4. Subject with a history of anorexia nervosa
5. Subject with prior any surgical therapy for obesity
6. Subject with diabetes, dyslipidemia, hypertension, cardiovascular disease and any other co-morbidity and considered as not healthy
7. Subjects on prolonged (greater than 6 weeks) product with corticosteroids, antidepressants, anticholinergics, antipsychotic drug etc. or any other drugs that may have an influence on the outcome of the study
8. Subjects suffering from major systemic illness necessitating long term drug product intake
9. Alcoholics and/or drug abusers
10. History of hypersensitivity to curcumin and wakame extract or any component of XTRA SLIM 700 formula
11. Pregnant/lactating woman

12. Subjects using other modulators like diet control, gym and yoga and wish to continue even after enrollment
13. Subjects having a history of psychiatric disorder that may impair the ability of subjects to provide written informed consent
14. Subjects who have completed participation in any other clinical trial during the past 3 months
15. Any other condition which the Principal Investigator thinks may jeopardize the study outcome

Date of first enrolment
01/11/2018

Date of final enrolment
18/01/2019

Locations

Countries of recruitment
Japan

Study participating centre
Medica Tokyo Laboratories
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Sponsor information

Organisation
INNOVATION LABO

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date.

IPD sharing plan summary
Not expected to be made available