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A study to evaluate the effect of orlistat + resveratrol combination on weight management

Submission date
22/06/2022

Recruitment status
No longer recruiting

Registration date
04/07/2022

Overall study status
Completed

Last Edited
02/09/2022

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Orlistat is intended to promote weight loss in addition to lifestyle modifications in overweight and obese individuals. Several patients taking orlistat do not achieve target weight loss despite adherence to therapy but lack adherence to exercise or diet modification. The addition of resveratrol to orlistat is intended to overcome these behavioral limitations leading to incremental metabolic benefits over orlistat alone.

Who can participate?
This study involves people aged 18 years or older with obesity/overweight (BMI more than or equal to 25 kg/m²).

What does the study involve?
The study involves treating people with obesity/overweight with either orlistat or orlistat + resveratrol for a period of 12 weeks.

What are the possible benefits and risks of participating?
The benefits of participating include active participation in weight reduction, while the risks include exposure to the side effects associated with orlistat (e.g. flatus with or without discharge).

Where is the study run from?
Defence Services General Hospital (Myanmar)

When is the study starting and how long is it expected to run for?
March 2022 to January 2023

Who is funding the study?
Zydus Lifesciences Ltd. (India)

Who is the main contact?
Dr Hardik Gandhi, hardikp.gandhi@zyduslife.com

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
EMB/MED/PRO/ORR/22/03/MY/01

Study information

Scientific Title
A prospective, post-marketing study to evaluate the efficacy and safety of orlistat + resveratrol combination (Zytrim-R)

Acronym
EC-FIT

Study objectives
Orlistat + resveratrol has better efficacy in terms of weight reduction as compared to orlistat in obese/overweight subjects

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 08/06/2022, Defence Services General Hospital Ethics Committee (Defence Services General Hospital, Mingaladon, Yangon 11021, Myanmar; +95 (0)95011780; tnaing69@gmail.com), ref: HRC2022/DSGH1/001

Primary study design
Interventional

Study design

Multicentre randomized controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Obesity and overweight

Interventions
Randomization: online tool for random sequence generation

Control arm: orlistat 120 mg hard capsules thrice daily
Test arm: orlistat 120 mg + resveratrol 100 mg hard capsules thrice daily

Duration of treatment: 12 weeks, Follow-up period: 12 weeks

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Orlistat, resveratrol

Primary outcome(s)
% of patients achieving more than or equal to 5% weight loss as compared to baseline. Weight will be measured using a digital weighing scale at baseline and 12 weeks.

Key secondary outcome(s)
1. Mean change in weight (Δ kg) measured using a digital weighing scale at baseline and 12 weeks
2. Skin fold thickness measured using a calliper at baseline and 12 weeks
3. Waist circumference measured using a measuring tape at baseline and 12 weeks
4. Body Mass Index (BMI) measured using the TANITA device at baseline and 12 weeks
5. Skeletal muscle mass, bone mass, visceral and total body fat measured using the TANITA device at baseline and 12 weeks
6. Daily caloric intake, metabolic age, and total body water measured using the TANITA device at baseline and 12 weeks
7. Resting blood pressure (systolic blood pressure [SBP] and diastolic blood pressure [DBP]) measured using a digital blood pressure monitor at baseline and 12 weeks
8. Lipid profile (minimum parameters LDL, HDL, TG and Total Cholesterol), HbA1c and liver function tests (AST and ALT) measured using a blood test at baseline and 12 weeks
9. Liver fat measured using FIBROSCAN at baseline and 12 weeks

Completion date
31/01/2023

Eligibility

Key inclusion criteria
1. Subjects of either sex (male or female) having age ≥18 years
2. Subjects with a BMI ≥25 kg/m² (overweight or obese) with or without metabolic syndrome (or components of metabolic syndrome like hypertension, type 2 diabetes, dyslipidemia or fatty liver) and prescribed orlistat or orlistat+resveratrol by their treating physician
3. Subjects and/or their legal guardian able to provide written informed consent and willing to comply with physician's instructions

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Subjects receiving orlistat other than Zytrim or Zytrim-R
2. Any contraindication for orlistat or orlistat + resveratrol as per the prescribing information
3. Subject simultaneously participating in any other clinical studies or having participated in any other clinical trial in the past 3 months (except survey-based studies)
4. History or other evidence of severe illness or any other conditions that would make the patient, in the opinion of the investigator, unsuitable for the study (such as poorly controlled psychiatric disease, HIV infection, or coronary artery disease)

Date of first enrolment
30/07/2022

Date of final enrolment
10/10/2022

Locations

Countries of recruitment
Myanmar

Study participating centre
Defence Services General Hospital
Mingaladon
Yangon
Myanmar
11021

Sponsor information

Organisation
Zydus Lifesciences Ltd

Funder(s)

Funder type
Industry

Funder Name
Zydus Lifesciences Ltd.

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Hardik Gandhi (hardikp.gandhi@zyduslife.com). The individual participant level data in anonymized will become available after publication of results. It will be available for researchers submitting a sound study design.

IPD sharing plan summary
Available on request