

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

<b>Submission date</b> 22/06/2022	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 04/07/2022	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 02/09/2022	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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/m<sup>2</sup>).

### 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](mailto:hardikp.gandhi@zyduslife.com)

# Contact information

## Type(s)

Scientific

## Contact name

Dr Hardik Gandhi

## ORCID ID

<http://orcid.org/0000-0001-8274-828X>

## Contact details

Zydus Corporate Park

Gujarat

India

382481

+91 7948040331

[hardikp.gandhi@zyduslife.com](mailto:hardikp.gandhi@zyduslife.com)

# Additional identifiers

## EudraCT/CTIS number

Nil known

## IRAS number

## ClinicalTrials.gov number

Nil known

## Secondary identifying numbers

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

### **Study design**

Multicentre randomized controlled trial

### **Primary study design**

Interventional

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Hospital

### **Study type(s)**

Treatment

### **Participant information sheet**

Not available in web format, please use contact details to request a participant information sheet

### **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 measure**

% 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.

### **Secondary outcome measures**

1. Mean change in weight ( $\Delta$  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

**Overall study start date**

12/03/2022

**Completion date**

31/01/2023

## Eligibility

**Key inclusion criteria**

1. Subjects of either sex (male or female) having age  $\geq 18$  years
2. Subjects with a BMI  $\geq 25$  kg/m<sup>2</sup> (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

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

264

**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

**Sponsor details**

Zydus Corporate Park

Ahmedabad

India

382481

+91 7948040331

hardikp.gandhi@zyduslife.com

**Sponsor type**

Industry

**Website**

<https://www.zyduslife.com/zyduslife/>

## **Funder(s)**

**Funder type**

Industry

**Funder Name**

Zydus Lifesciences Ltd.

## **Results and Publications**

**Publication and dissemination plan**

Planned publication in a high impact peer-reviewed journal

**Intention to publish date**

31/01/2024

**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](mailto: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