

1-year at home diet and exercise interventions in ER+ breast cancer patients

Submission date 03/07/2016	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 09/07/2016	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 24/01/2019	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims:

It's common for women having chemotherapy and antiestrogenic treatment for breast cancer to gain weight. This can increase the risk of the cancer coming back and death due to the fact that they can aggravate insulin and leptin (a hormone produced by the body's fat cells) resistance, as well as dysbiosis (a term used to describe microbial imbalance in the gut) and dyslipidemia (increase through osteosarcopenia). Also, the emotional impact of either conservative surgery or mastectomy can theoretically influence these patients' eating behavior and willingness to exercise in order to reverse this weight gain. This home-based study aims to answer three questions:

1. Is a high protein diet effective for fat loss in ER+ breast cancer patients on antiestrogenic medication?
2. Is the addition of only 4 minutes of daily isometric exercises to this high protein diet more effective to improve their body composition?
3. How does the surgery, chemotherapy and antiestrogenic medication type influence the effects of these interventions?

Who can participate?

Overweight women with breast cancer who are currently being treated with antiestrogenic treatment after surgery and chemotherapy

What does the study involve?

Participants are randomly allocated to one of two groups. Those in group 1 follow an at home diet based on food rich in protein, calcium, omega-3 fatty acids, probiotics and prebiotics for one year. Those in group 2 follow the same diet but also do 4' isometric exercises for one year. All participants have their total body weight, body fat and visceral fat (belly fat) six months into the study and again at the end of the study (one year).

What are the possible benefits and risks of participating?

The diet was made up of easily affordable foods and the exercises were highly accepted. It is hoped that these will lead to an improvement in body composition and general wellbeing. All participants were closely supervised for the first two months of the study so that any associated risk of taking part would be reduced to minimum.

Where is the study run from?

"Prof. Dr. Al. Trestioreanu" Institute of Oncology (Romania)

When is the study starting and how long is it expected to run for?

February 2015 to April 2016

Who is funding the study?

European Social Fund

Who is the main contact?

Mrs Diana Viorela Arterne

Contact information

Type(s)

Scientific

Contact name

Mrs Diana Viorela Arterne

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077010

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

1

Study information

Scientific Title

Comparative results of 1-year at home diet and exercise interventions in ER+ breast cancer patients correlated with treatment type

Study objectives

This home-based study aims to answer three questions:

1. Is a high protein diet effective for fat loss in ER+ breast cancer patients on antiestrogenic medication?
2. Is the addition of only 4 minutes of daily isometric exercises to this high protein diet more effective to improve their body composition?
3. How does the surgery, chemotherapy and antiestrogenic medication type influences the effects of these interventions?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee of the "Prof. Dr. Al. Trestioreanu" Institute of Oncology, Bucharest, Romania, ref: 4555/18.03.2016.

Study design

Single center interventional randomised parallel trial

Primary study design

Interventional

Secondary study design

Randomised parallel trial

Study setting(s)

Home

Study type(s)

Prevention

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

ER+/PR±/HER2- breast cancer

Interventions

Overweight patients with ER+/PR±/HER2- luminal A and B breast cancer, currently under antiestrogenic treatment after surgery and chemotherapy - without diabetes, thyroid or renal disease, eating disorders, depression and osteoporosis were selected for this study. They were randomly allocated into one of two groups.

1. Participants follow an at home diet based on food high in proteins, calcium, omega-3 fatty acids, probiotics and prebiotics (D) for one year

2. Participants follow the same diet as those in group 1 in combination with 4' isometric exercises (D+Ex) for one year

Total body weight, body and and visceral fat were measured for all participants using a multi-frequency bioelectrical impedance scale after 6 months and after 12 months. The results were then correlated with the study intervention and with the type of antiestrogenic medication, surgery and chemotherapy.

Intervention Type

Behavioural

Primary outcome measure

Total body weight, body and visceral fat using a multi-frequency bioelectrical impedance scale at 6 months and 12 months

Secondary outcome measures

N/A

Overall study start date

01/02/2015

Completion date

01/04/2016

Eligibility**Key inclusion criteria**

1. Overweight patients with ER+/PR±/HER2- luminal A and B breast cancer
2. Currently under antiestrogenic treatment after surgery and chemotherapy

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

165 patients: 83 in the Diet intervention group and 82 in the D+Ex intervention group

Key exclusion criteria

1. Diabetes
2. Thyroid or renal disease
3. Eating disorders
4. Depression
5. Osteoporosis

Date of first enrolment

01/02/2015

Date of final enrolment

15/02/2015

Locations

Countries of recruitment

Romania

Study participating centre

"Prof. Dr. Al. Trestioreanu" Institute of Oncology

Șoseaua Fundeni 252

Bucharest

Romania

022328

Sponsor information

Organisation

Carol Davila Medicine University

Sponsor details

Dionisie Lupu Street no.37

District 2

Bucharest

Romania

020021

Sponsor type

University/education

Website

<http://www.umf.ro>

ROR

<https://ror.org/04fm87419>

Funder(s)

Funder type

Government

Funder Name

European Social Fund

Alternative Name(s)

Европейският социален фонд, Evropský sociální fond, Den Europæiske Socialfond, Europäischer Sozialfonds, Euroopa Sotsiaalfond, Ευρωπαϊκό Κοινωνικό Ταμείο, Fondo Social

Europeo, Fonds social européen, Europski socijalni fond, Fondo sociale europeo, Eiropas Sociālais fonds, Europos socialinis fondas, Európai Szociális Alap, Fond Soċjali Ewropew, Europees Sociaal Fonds, Europejski Fundusz Społeczny, Fundo Social Europeu, Fondul Social European, Európsky sociálny fond, Evropski socialni sklad, Euroopan sosiaalirahasto, Europeiska socialfonden, European Social Fund, Fondo Social Europeo Plus, Европейски социален фонд плюс, Evropský sociální fond plus, Europæiske Socialfond Plus, Europäische Sozialfonds+, Euroopa Sotsiaalfond+, Ευρωπαϊκό Κοινωνικό Ταμείο+, Fonds social européen+, Europski socijalni fond plus, Fondo sociale europeo Plus, Eiropas Sociālais fonds Plus, Europos socialinis fondas +, Európai Szociális Alap Plusz, Europees Sociaal Fonds Plus, Europejski Fundusz Społeczny Plus, Fundo Social Europeu Mais, Fondul social european Plus, Európsky sociálny fond +, Evropski socialni sklad +, Euroopan sosiaalirahasto plus, Europeiska socialfonden+, ESF, ECΦ, EKT, FSE, ESZA, EFS, ESS, ESR, ESF+, ESZA+, EFS+, FSE+, ESS+, ESR+

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Results and Publications

Publication and dissemination plan

To be confirmed at a later date

Intention to publish date

01/04/2017

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2017	24/01/2019	Yes	No