ISRCTN12929438 https://doi.org/10.1186/ISRCTN12929438

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

Submission date
03/07/2016

Recruitment status
No longer recruiting

Registration date
09/07/2016

Overall study status
Completed

Last Edited
24/01/2019

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims:
Its 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 influences 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 led 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 2915 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
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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 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, ЕСФ, 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