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Breast Risk Reduction Intermittent Diet Evaluation (BRRIDE) study

Submission date	Recruitment status	[_] Prospectively registered
21/06/2012	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
31/07/2012	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
31/05/2016	Cancer	

Plain English summary of protocol

Background and study aims

Breast cancer is unfortunately very common, approximately 1 woman in 9 in the UK develops breast cancer at some point her lifetime. We know that being overweight increases the chances of developing breast cancer, whilst research has shown that losing weight reduces risk. Researchers at the Genesis Prevention Centre are trying to find the best weight loss diet to reduce risk of breast cancer. We have found that an intermittent diet (a very low calorie diet for two consecutive days per week followed by a healthy eating with no restriction on the other five days) helps women to lose weight. We now wish to look at the effects of the diet within the breast and other tissues in the body. The pattern of genes (the instructions in all of the cells in our bodies) that are active, or 'expressed' within a healthy women's breast when they follow the diet, as well as other changes in blood and urine markers of cancer risk will indicate whether the diet is likely to help reduce risk of breast cancer.

Who can participate?

We are seeking to recruit 25 women attending the Family History Clinic at the Genesis Prevention Centre who would like to lose weight and are otherwise well. To join the study you must: have a family history of breast cancer (lifetime risk >1 in 6), have a body mass index (BMI) 2435 kg/m2, be aged between 35 and 45 years, have regular menstrual cycles (not perimenopausal), have breast density >30% determined by mammogram, be sedentary (<20 minutes moderate activity twice/ week), be able to record diet diaries, have had a normal mammogram in the last 2 years.

What does the study involve?

All participants will be asked to follow an intermittent weight losing diet for approximately five weeks. This intermittent very low calorie diet involves eating a very low calorie diet (600 calories or kcal each day) for two consecutive days of the week and a healthy eating diet of around 1800-2000 kcal each day for the remaining 5 days. The normal suggested daily intake for a woman in the UK is approximately 1800-2000 kcal. You will be asked to attend the Nightingale Centre and Genesis Prevention Centre for 4 visits, have 2 breast biopsies and 3 fasting blood tests. You will be asked to complete a food and activity diary during the week before you start and during your fourth week on the diet.

What are the possible benefits and risks of participating?
The diet is very safe and will meet all your nutritional needs except that it is low in calories. The breast biopsies may cause some bruising. A small dose of x-rays is used to locate the tissue in the breast, which is considerably less than you receive when you have a mammogram. You will almost certainly lose some weight whilst participating in this diet study. This may reduce your risk of developing breast cancer and other weight related health problems such as diabetes and heart disease, providing that you manage to maintain the weight loss. We will give you advice on how to do this. You will be contributing to our knowledge about the effects of weight loss on breast cancer risk. At the end of the study once the analysis has been done we will let you know your own blood results. Some of the substances we analyse are well-known markers of health, such as insulin and blood sugar, and blood fats such as cholesterol. If these are out of the recommended range we will be able to advise you or refer you on to your GP for further tests or advice. Please note that gene expression studies are not the same as genetic testing and will not tell us anything about genetic changes that can be inherited from or passed on to other family members. Therefore our findings will have no implications for your insurance policies or for your relatives.

When does the study take place?
The Nightingale Centre and Genesis Prevention Centre, Wythenshawe Hospital, Manchester, UK.

When is the study starting and how long is it expected to run for?
The study started in February 2010 and ended in October 2010.

Who is funding the study?
The Genesis Appeal, UK ref: GA 08020

Who is the main contact?
Dr Michelle Harvie
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
2009BR003

Study information

Scientific Title
The Breast Risk Reduction Intermittent Diet Evaluation (BRRIDE) study: The effect of an intermittent very low calories diet on gene expression in breast cells and surrogate blood markers of risk amongst women at increased risk of breast cancer

Acronym
BRRIDE

Study objectives
We hypothesise that two day intermittent energy restriction (IER) will bring about significant changes within the breast and surrogate tissues over one month.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee North West - Greater Manchester North, 09/06/2009

Study design
Single-centre non-randomised study

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Breast cancer

Interventions
25 subjects will be asked to follow a two day IER diet for 1 month which involves a 70% restriction (~600kcal/ day) for 2 days week and ~1850 kcal for 5 days/week.

The non very low calorie diet (VLCD) days are based on a Mediterranean type diet (30% energy from fat, 15% MUFA 7% from saturated fat, 7% PUFA, low glycaemic load). The 600 kcal diet comprises 2 pints of semi skimmed milk, 3 portions of vegetables, 2 portions of fruit, one salty low calorie drink, at least 2 pints of other low energy fluid, and a multivitamin and mineral supplement.

Adherence to the diet will be assessed from weight change over the 4 weeks and a 7 day food diary in the fourth week. Participants will be advised to maintain current levels of activity which will be assessed prospectively using an accelerometer during week 4 (Actigraph USA).

Intervention Type
Behavioural

Primary outcome(s)

Expression of genes which produce the fat synthesis protein (Stearoyl-CoA desaturase) in breast cells of women after 1 month of a 2 day/week very low calorie diet.

Key secondary outcome(s))
1. Expression of 19 other proteins which process fat and carbohydrate in breast tissue and may be linked to breast cancer risk
2. Expression of proteins which process fat and carbohydrate in white blood cells
3. Hormones, proteins and fats and other products of metabolism in blood and urine

Completion date
19/10/2010

Eligibility

Key inclusion criteria
1. Family history of breast cancer (lifetime risk >1 in 6)
2. Body mass index 2435 kg/ m2
3. Aged between 35 and 45 years
2. Regular menstrual cycles (not perimenopausal).
3. Breast density >30% determined by mammogram (to ensure epithelium is obtained in core biopsy)
5. Sedentary (<20 minutes moderate activity twice/ week) to avoid any confounding effects of exercise
6. Able to record diet diaries
7. Normal mammogram in the last 2 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
1. Already successfully dieting or losing weight
2. Long term medical condition which may affect white cell function; i.e. autoimmune, inflammatory, allergy
3. Consumption of diets or supplements high in phytoestrogens
4. Previous use of tamoxifen or other selective oestrogen receptor modulators
5. Current use of anticoagulant or anti-platelet drugs including regular aspirin
6. Previous diagnosis of breast cancer or other cancers except non-melanoma skin cancer or cervical intra-epithelial neoplasia
7. Previous atypical ductal hyperplasia or Atypical Lobular Hyperplasia
8. Pregnant or planning a pregnancy in the next few months
9. Irregular menstrual cycles with the possibility of perimenopausal status

10. Use of hormonal oral contraceptives or progesterone only contraceptives (Intra-uterine system (Mirena), injectable or implantable progesterones) currently or in the past 6 months.
11. Serious co-morbidity that would in the opinion of the investigator confound the results of the study or put the patient at risk, such as diabetes mellitus, ischaemic heart disease, thyroid disease
12. Psychiatric morbidity (eating disorders, depression or alcoholism)
13. Previous breast enhancement or breast reduction surgery
14. Received inoculations or donated blood within 2 months of the start of the study

Date of first enrolment
11/02/2010

Date of final enrolment
19/10/2010

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
The Nightingale Centre and Genesis Prevention Centre
Manchester
United Kingdom
M23 9LT

Sponsor information

Organisation
University Hospital of South Manchester (UHSM) NHS Foundation Trust (UK)

ROR
https://ror.org/00he80998

Funder(s)

Funder type
Charity

Funder Name

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	28/05/2016		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes