Protocol Registration Preview

This is a rough approximation of how the Protocol Registration will appear on the ClinicalTrials.gov public web site.

Evaluation of Homeopathic Treatment for Hot Flashes in Non Metastatic Breast Cancer (HBC)

ClinicalTrials.gov Identifier: NCT01246427

Recruitment Status: Completed
First Posted: *
Last Update Posted: *

* Date not available in PRS

Sponsor:

Centre Leon Berard

Collaborators:

BOIRON

Information provided by (Responsible Party):

Centre Leon Berard

Study Description

Brief Summary:

The purpose of this study is to evaluate the efficacy of a homeopathic treatment (BRN01) in reducing hot flash scores after 4 weeks of treatment.

Condition or disease	Intervention/treatment	Phase
Breast Cancer	Drug: BRN01 Drug: Placebo	Phase 3

Detailed Description:

Chemotherapy is used as an adjuvant treatment for breast cancer, like hormone therapy in patients with hormone-sensitive breast cancer or immunotherapy in those with Human Epidermal growth factor Receptor 2 (HER2)-overexpressing cancer.

These adjuvant treatments reduce the risk of recurrence and metastasis. The side effects of hormone therapy are known and depend on the therapeutic strategy and the drugs used. The side effects of Tamoxifen are similar to menopausal symptoms: hot flashes (half of the female population), vaginal dryness or leukorrhea, nausea, irregular menstruation, benign ovarian cyst and, less frequently, weight gain. Aromatase inhibitors have the same side effects, though with lesser frequency and intensity. The incidence rate of hot flashes after adjuvant treatment in menopausal women with localized breast cancer is 60 to 65 %, and these reactions are very severe in one third of these women. Despite this fact, the management of hot flashes is not systematic and there is currently no therapeutic strategy with proven efficiency. BRN01 (Boiron laboratory) is a homeopathic remedy whose active ingredient is already present in other homeopathic drugs indicated for the management of menopausal hot flashes. BRN01 could reduce the intensity of the reaction in women with breast cancer receiving adjuvant hormonal treatment.

Study Design

Study Type:	Interventional
Actual Enrollment:	138 participants
Allocation:	Randomized
Intervention Model:	Parallel Assignment
Masking:	Double (Participant, Investigator)
Primary Purpose:	Treatment
Official Title:	Placebo-controlled Evaluation of the Homeopathic Drug BRN01 for the Treatment of Hot Flashes in Women With Non Metastatic Breast Cancer Treated by Adjuvant Hormonal Therapy
Study Start Date:	January 2010
Actual Primary Completion Date:	May 2014
Actual Study Completion Date:	November 2014

Arms and Interventions

Arm	Intervention/treatment

Experimental: BRN01 A 2 to 4 weeks run-in period is planned, during which all patients receive single blinded "hot flash evaluation treatment" which is actually a placebo (2 tablets every morning and every evening during 2 to 4 weeks). At the end of this period, the hot flash score is calculated. If the score is ≥10, the patient can be randomized to one of the 2 arms: • Experimental: BRN01 • Placebo Comparator: Placebo	Drug: BRN01 2 tablets every morning and every evening during 8 to 10 weeks. Each patient will receive 1 set of 5 treatment boxes (60 tablets/box).
Placebo Comparator: Placebo A 2 to 4 weeks run-in period is planned, during which all patients receive single blinded "hot flash evaluation treatment" which is actually a placebo (2 tablets every morning and every evening during 2 to 4 weeks). At the end of this period, the hot flash score is calculated. If the score is ≥10, the patient can be randomized to one of the 2 arms: • Experimental: BRN01 • Placebo Comparator: Placebo	Drug: Placebo 2 tablets every morning and every evening during 8 to 10 weeks. Each patient will receive 1 set of 5 treatment boxes (60 tablets/box).

Outcome Measures

Primary Outcome Measure:

1. Evaluation of BRN01 efficacy in reducing hot flash score after 4 weeks of treatment [Time Frame: The patients are instructed to record the number and intensity of hot flashes in a self-evaluation booklet every day during the 2nd week of the first period (run-in period) and during the 4th week of the second period (placebo or BRN01).]

   The hot flash score is equal to: (number of hot flashes/day) x (mean intensity/day).

   Treatment efficiency scores will be calculated as follows: (hot flash score on the 4th week of the second period)-(hot flash score on the 2nd week of the first period).

   Then efficiency scores will be compared between the 2 arms (placebo versus BRN01).

Secondary Outcome Measures:

1. Evaluation of BRN01 efficacy in reducing the hot flash score after 8 weeks of treatment [Time Frame: The patients are instructed to record the number and intensity of hot flashes in a self-evaluation booklet every day during the 2nd week of the first period (run-in period) and during the 8th week of the second period (placebo or BRN01).]

   Treatment efficacy scores will be calculated as follows: (hot flash score on the 8th week of the second period)-(hot flash score on the 2nd week of the first period).

   Then efficiency scores will be compared between the 2 arms (placebo versus BRN01).

2. Evaluation of the mean daily intensity of hot flashes during the run-in period and on the 4th and 8th weeks of treatment in both arms. [Time Frame: The patients are instructed to record the intensity of hot flashes in a self-evaluation booklet, daily, during the 2nd

week of the first period (run-in period), and during the 4th and 8th weeks of the second period (placebo or BRN01).]

3. Evaluation of the mean daily frequency of hot flashes during the run-in period and on the 4th and 8th weeks of treatment in both arms. [Time Frame: The patients are instructed to record the number of hot flashes in a self-evaluation booklet, daily, during the 2nd week of the first period (run-in period), and during the 4th and 8th weeks of the second period (placebo or BRN01).]

4. Evaluation of quality of life in both arms [Time Frame: The patients are instructed to complete quality of life items on the 7th day of each evaluation period (2nd week of the run-in period, 4th and 8th weeks of the second period)]

5. Evaluation of patient satisfaction with the treatment and with the management of hot flashes. [Time Frame: The patients are instructed to record all new hot flash treatments started, as well as their satisfaction with their management, on the 7th day of each evaluation period (2nd week of the run-in period, 4th and 8th weeks of the second period).]

6. Evaluation of treatment tolerance [Time Frame: Side effects are registered by the oncologist at each visit (planned during the 3rd week or the 4th week of the run-in period and during the 9th week or the 10th week of the second period)]

7. Evaluation of patient compliance [Time Frame: The number of remaining tablets will be counted at each visit (planned during the 3rd week or the 4th week of the run-in period and during the 9th week or the 10th week of the second period)]

Eligibility Criteria

Ages Eligible for Study: 18 Years and older

Sexes Eligible for Study: Female

Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Female patient aged ≥ 18 years
- Women with histologically proven non metastatic breast cancer
- ECOG PS ≤ 1
- Patient receiving adjuvant hormonal therapy for at least 1 month (aromatase inhibitor or Tamoxifen ± ovarian function suppression (Luteinizing Hormone Releasing Hormone agonist (LH-RH agonist), ovariectomy...))
- Patient complaining of hot flashes with moderate to severe intensity, affecting quality of life, for at least 1 month before inclusion
- Patient agreement not to start another hot flash treatment during the study (allopathic treatment, E vitamin, dietary supplement, phytotherapy, acupuncture...)
- Patient able to understand, read and write French
- Mandatory affiliation with a health insurance system
- Signed, written informed consent

Exclusion Criteria:

- Ongoing chemotherapy or radiotherapy, or treatment planned to begin during the study
- Patient with a condition known to induce hot flashes such as hyperthyroidism, diabetes, adrenal tumor, enteric carcinoid tumor, mastocytosis...
- Patient with severe renal failure, severe hepatic failure, or cardiovascular disease
- Patient with one of the following contraindications:
  - known hypersensitivity to one of the components of the study drug
  - galactose, fructose intolerance
  - Lapp lactase deficiency, isomaltase invertase deficiency
  - Glucose or galactose malabsorption syndrome
- Follow up impossible because of social, familial, geographical or psychological reasons
- Patient suspected of poor compliance with protocol or treatment
- Participation in another biomedical research trial in the same indication, or administration of an experimental drug in the same indication in the 30 days before inclusion

Contacts and Locations

Locations

France

Centre Hospitalier de Chambery
Chambery, France

Centre Jean Perrin
Clermont Ferrand, France

Centre Leon Berard
Lyon, France, 69373

Centre Hospitalier de Montelimar
Montelimar, France

Centre Hospitalier d'Annecy
Pringy, France

Centre Hospitalier de Roanne
Roanne, France

Clinique Armoricaine de radiologie
St Brieuc, France

Institut de Cancérologie Lucien Neuwirth
St Priest en Jarez, France

Centre Hospitalier de Valence
Valence, France

Investigators

Principal Investigator: Pierre Etienne Heudel, MD Centre Leon Berard, France

More Information

Publications:

Remontet L, Estève J, Bouvier AM, Grosclaude P, Launoy G, Menegoz F, Exbrayat C, Tretare B, Carli PM, Guizard AV, Troussard X, Bercelli P, Colonna M, Halna JM, Hedelin G, Macé-Lesec'h J, Peng J, Buemi A, Velten M, Jougla E, Arveux P, Le Bodic L, Michel E, Sauvage M, Schvartz C, Faivre J. Cancer incidence and mortality in France over the period 1978-2000. Rev Epidemiol Sante Publique. 2003 Feb;51(1 Pt 1):3-30.

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