

# Use of homeopathy in the treatment of menopausal symptoms in patients operated for early breast cancer



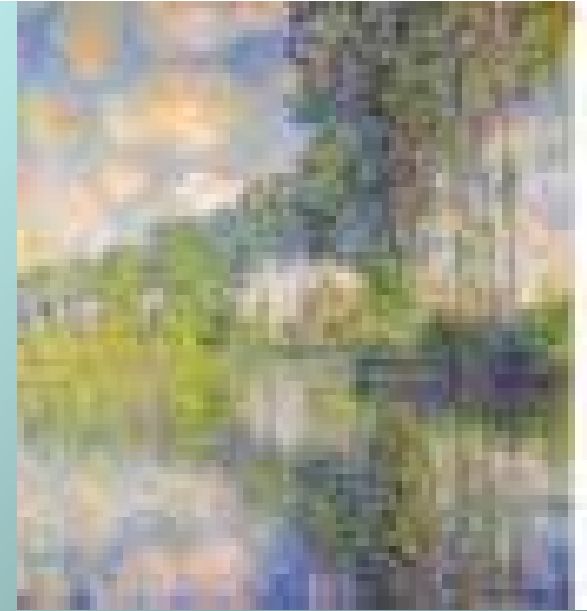
**Dr. Franco Desiderio XXIII IATMO Conference-Trieste**

# Introduction-1



**Menopausal symptoms represent an important problem for many young women with breast cancer. These symptoms have a great influence on the quality of life of the patients.**

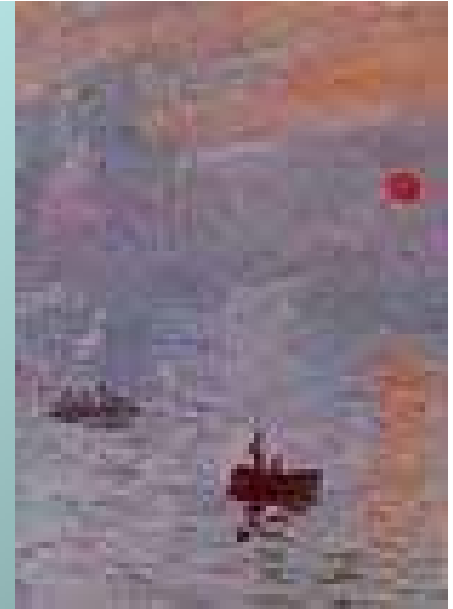
## **Introduction-2**



**The necessity of a treatment for the menopausal symptoms is discussed since hormonal replacement therapy for these patients is absolutely contraindicated.**

**Many clinical trials are ongoing studying alternative treatments.**

# Homeopathic treatment



**Some homeopathic remedies seem to be able to affect through different mechanisms the climacteric neuro-vegetative and somatic symptoms without changing the hormonal level in the blood.**

# **Climacteric symptoms: neuro-vegetative**

**Hot flushes**

**Sweating**

**Insomnia**

**Palpitation-tachycardia**

**Cephalalgia-dizziness**

**Tiredness**

**Periferic circulation disorders**

**Hypertension**

**etc.**

Probably related to the neurotransmitters:  
serotonine, dopamine, other.



# **Climacteric symptoms: psychological**

**Reduced**

**-concentration**

**-libido**

**-intellectual capacity**

**Increased**

**- tension**

**- irritability and aggressiveness**

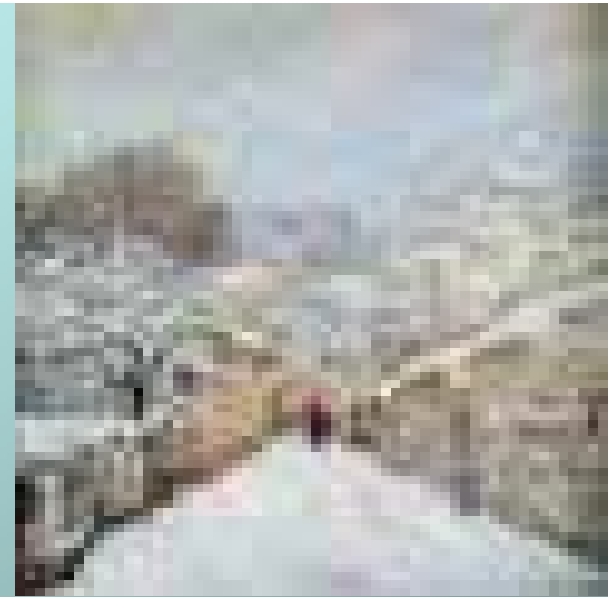
**- mood lability**

**Depression**

# **Climacteric symptoms: Organic**

- **Atrophic changes in the vagina, vulva, urethra and bladder**
- **uterine and bladder prolapse**
- **urinary incontinence**
- **generalized atrophy**
- **increased bone reabsorption**
- **increased total cholesterol + LDL**
  
- **(symptoms that are revealed in late menopause)**

## **Study objectives:**



**Evaluate the efficacy of a homeopathic treatment for menopausal symptoms in women operated for breast cancer**

# Eligibility criteria

- **Patients operated for breast cancer without metastatic disease.**
- **Patients may have received chemotherapy.**
- **Patients may be receiving endocrine therapy (tamoxifen or aromatase inhibitors).**
- **Patients with menopausal symptoms.**
- **Written informed consent.**
- **Patients must be accessible for follow-up.**

# Study design

**The study is composed of two different phases:**

- **Phase A Pilot study:** Enrollment of 10 patients treated with the homeopathic remedy for 3 months (completed)
- **Phase B Randomized study:** Enrollment of 30 patients treated with the homeopathic remedy or placebo for 6 months (ongoing)

# Homeopathic treatment

## Phase A



**The patients enrolled in the phase A study received 3 tablets/day for 3 months. The tablets were administered sublingually and the patients were asked to masticate the tablets before swallowing them.**

**Comp.:1 tablet of 0,25 g contains: Cimicifuga D2 25mg, Sepia D2 25mg, Ignatia D3 25mg, Sanguinaria D2 25mg.  
Eccipienti: lactose, amide, Mg stearate**

# HOMEOPATHIC REMEDIES



**CIMICIFUGA:** is prescribed in homeopathy for several symptoms related to the female endocrine system. For example: menstrual problems, depression, hot flushes, palpitations, precordial pain from muscle spasms, etc...



**SEPIA:** regulates the interaction of the hormones of the adrenals, the sex organs and the hypophysis and acts especially on the psychological sphere (depression, mood alteration, irritability) but also sweating, hot flushes and insomnia.



**IGNATIA AMARA:** is used particularly for treatment of mood swings, bad mood, depression, irritability and sleeping problems.

**SANGUINARIA CANADENSIS:** good efficacy on vasomotor symptoms such as hemicrania, hot flushes, increased cardiac activity. It is also indicated for climacteric metrorrhagia.

## **Baseline visit (Time 0)**

- **Written informed consent**
- **Registration of the patient (date of birth, weight, height, date of last menstrual cycle, the type of menopause (natural/chemical)).**
- **Date of the diagnosis of breast cancer.**
- **Chemotherapy: yes/no, the type of chemotherapy, start and end date.**
- **Endocrine therapy: type of hormonal therapy and start date of treatment.**
- **Menopausal symptoms using the NCI-CTC scale.**

## **Follow-up visit (Time 1)**



**The same assessments of the menopausal symptoms were done at 3 months from the start of the treatment for the patients in the phase A study and at 3 months and 6 months for the patients in the phase B study.**

## **Treatment in phase B**

**In the phase B study the homeopathic remedy is in alcoholic solution with the same composition as in the phase A study, administered as 20 drops 3 times/day for 6 months.**

**20 drops contain: Cimicifuga D2, Sepia D2, Ignatia D3, Sanguinaria D2 ANA PARTI. Excipient: 30% alcoholic solution.**

**Placebo: 30% alcoholic solution.**

<b>Menopausal symptom:</b>	<b>0</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>
Hot flushes	No	Mild or 1/day	Moderate	Severe	
Nocturnal sweating	No	Mild	Frequent		
Leukorrhoea	No	Mild	Moderate	Severe	
Atypical vaginal bleeding	No	Mild, < 2 pads/day	> 2 pads/days, no transfusion	Transfusion needed	Important bleeding
Vaginal dryness	No	Mild	Treatment needed		
Dispareunia	No	Mild	Moderate, interfering with sexual function	Severe, sexual function impossible	
Gastric symptoms	No	Mild	Moderate	Severe	
Dermatological alteration	No	Mild	Moderate	Severe	
Headache	No	Mild, not interfering with normal activity	Moderate, not interfering with ADL	Severe, interfering with ADL	Disabling
Hydric retention	No	Mild	Moderate	Severe	
Anxiety-depression	No	Mild	Moderate	Severe	
Other, specify .....					

## **Criteria for evaluation of the response (Phase A)**

**The patients were contacted after 3 months for assessment of the symptoms using the NCI-CTC**

**The grades of the symptoms were added together to obtain a total score at baseline and after 3 months**

**The score had a minimum value of 1 and a maximum value of  $\geq 26$ .**

**The same procedure is used in the phase B study with the only difference that the assessment is done after 3 months as well as 6 months.**



## **Data analyses**

- **The patients are evaluated according to the "Intention to treat".**
- **Qualitative variables are analyzed in terms of frequency and the quantitatives in terms of mean, median and standard deviation.**
- **For the statistical analysis a non parametric statistical test and analysis of covariance will be used.**
- **The statistical tests are two-tailed; the level of statistical significance is considered as  $P < 0,05$ .**



## **Results of Phase A study (I)**

- In the pilot study 10 patients were treated with the homeopathic remedy. The symptoms were assessed at baseline before starting the treatment (time 0) and after 3 months of treatment (time 1).**
- The assessed symptoms according the NCI-CTC were: hot flushes, nocturnal sweatings, leukorrhoea, atypical vaginal bleeding, vaginal dryness, dyspareunia, gastric symptoms, dermatological alterations, headache, hydric retention, anxiety/depression and other symptoms.**

## **Results phase A (2)**



**On 78 reported symptoms at baseline (mean 7.8 symptoms/patient, min 5 and max 11 / patient), we obtained: 57 decrease of the symptoms of at least one point (73%), 17 stable symptoms (21.8%) and 4 increase in at least one point (5.2%).**

## Results phase A (3)



- The scores of each symptom were added together to obtain a total score for each patient at time 0 and at time 1.
- We observed a reduction of the symptoms in all patients (mean reduction of the score was 8.5, SD 4.8, range 2-15) and a statistically significant difference in the score reduction (paired t-test,  $p < 0,001$ ).

## Results phase A (4)

<b>Menopausal symptom:</b>	<b>T0</b>	<b>T1</b>	<b>T1-T0</b>
<b>Hot flushes</b>	<b>27</b>	<b>10</b>	<b>-17</b>
<b>Nocturnal sweating</b>	<b>20</b>	<b>9</b>	<b>-11</b>
<b>Leukorrhoea</b>	<b>5</b>	<b>3</b>	<b>-2</b>
<b>Atypical vaginal bleeding</b>	<b>0</b>	<b>0</b>	<b>0</b>
<b>Vaginal dryness</b>	<b>11</b>	<b>4</b>	<b>-7</b>
<b>Dispareunia</b>	<b>8</b>	<b>3</b>	<b>-5</b>
<b>Gastric symptoms</b>	<b>13</b>	<b>7</b>	<b>-6</b>
<b>Dermatological alteration</b>	<b>2</b>	<b>0</b>	<b>-2</b>
<b>Headache</b>	<b>18</b>	<b>11</b>	<b>-7</b>
<b>Hydric retention</b>	<b>11</b>	<b>6</b>	<b>-5</b>
<b>Anxiety/depression</b>	<b>12</b>	<b>6</b>	<b>-6</b>
<b>other.....</b>	<b>31</b>	<b>15</b>	<b>-16</b>
<b>SCORE</b>	<b>158</b>	<b>74</b>	<b>-84</b>

# Conclusions

- All women participating in the study had both physical as well as psychological benefits of the therapy
- No adverse events were observed
- Major part of the women are continuing the therapy independently.



## Conclusions(2)

Considering the results from the pilot study it was decided to proceed with the randomized phase B study.

So far 15 women have been enrolled in the study.



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**THE WOMEN THAT HAVE PARTICIPATED IN THIS  
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