

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

22 Jan 2022

### Randomized double blind placebo controlled study of oral lithium for prevention of chemotherapy induce peripheral neuropathy in breast cancer patients under treatment by Taxans and Platinum base medicines

#### Protocol summary

##### Study aim

Determination of lithium effectiveness in prevention of peripheral neuropathy in breast cancer patients under treatment with Taxans and Platinum base medicines

##### Design

Clinical trial, placebo control, parallel group, double blind, randomized

##### Settings and conduct

Place of study: Field of study: clinical, randomized, double\_blind, placebo control Method of study: Between breast cancer patients, we will choose people with inclusion criteria. They will be divided into 2 groups of medicine and placebo by randomization. First group will receive oral 300 mg lithium one day before every chemotherapy cycle up to 5 days later and second group will receive placebo one day before every chemotherapy cycle up to 5 days later. From all patients in this study, we will take EMG\_NCV and scoring of peripheral neuropathy, before starting the first chemotherapy cycle, 3 months later, 6 months later and 1 year later. Blinding: In this study, patients and main researcher have blinded and they don't have information that each patient in which group has settled.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria : Breast cancer women between 18 to 60 years old Exclusion criteria : Dissatisfaction of patients to participate in study Pregnant and breastfeeding women and also women with intention of pregnancy Patients with peripheral nerves disorders, renal, thyroid, and cardiovascular disorders, diabetes, bipolar

##### Intervention groups

Intervention group : People in this group will receive 300 mg oral lithium daily, one day before every chemotherapy cycle up to 5 days later Control group : People in this group will receive placebo daily, one day before every chemotherapy cycle up to 5 days later

#### Main outcome variables

Breast cancer, chemotherapy, prevention, peripheral neuropathy, lithium, EMG\_NCV , scoring of peripheral neuropathy

#### General information

##### Reason for update

##### Acronym

CIPN=Chemotherapy Induce Peripheral Neuropathy

##### IRCT registration information

IRCT registration number: **IRCT20160813029327N10**

Registration date: **2018-05-16, 1397/02/26**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-05-16, 1397/02/26**

Update count: **0**

##### Registration date

2018-05-16, 1397/02/26

##### Registrant information

##### Name

Ramin Abrishami

##### Name of organization / entity

Islamic Azad University, Pharamceutical sciences branch

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2264 1889

##### Email address

r\_abrishami@iaups.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-04-29, 1397/02/09

**Expected recruitment end date**

2019-06-21, 1398/03/31

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Randomized double blind placebo controlled study of oral lithium for prevention of chemotherapy induce peripheral neuropathy in breast cancer patients under treatment by Taxans and Platinium base medicines

**Public title**

Assessment of efficacy of lithium in prevention of peripheral neuropathy

**Purpose**

Prevention

**Inclusion/Exclusion criteria****Inclusion criteria:**

Women with breast cancer between 18 to 60 years old

**Exclusion criteria:**

Dissatisfaction of patients to participate in the study  
Pregnant or planning for pregnancy and nursing mothers  
Patients with peripheral nerves disorders, renal disorders, thyroid disorders, cardiovascular disorders, diabetes, bipolar

**Age**

From **18 years** old to **60 years** old

**Gender**

Female

**Phase**

3

**Groups that have been masked**

- Participant
- Investigator

**Sample size**

Target sample size: **44**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In this study by using specialized randomization method and daily references list, patients with inclusion criteria, by chance and in quadruple blocs, divided into 2 groups: A and B Patients with "A" CARD will enter into intervention group (chemotherapy + lithium) and patients with "B" CARD will enter into control group (chemotherapy + placebo).

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

In this double\_blind investigation, participating patients and main researchers have remained blinded and they don't have information toward setting patients in intervention group or control group.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Teheran Islamic Azad University of Pharmaceutical sciences

**Street address**

No 99, Yakhchal Street, Gholhak Area, Shariati Ave

**City**

Tehran

**Province**

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**Postal code**

6466\_19395

**Approval date**

2017-09-23, 1396/07/01

**Ethics committee reference number**

IR.IAU.PS.REC.1396.102

**Health conditions studied****1****Description of health condition studied**

Chemotherapy induce peripheral neuropathy

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

1) Comparison of EMG\_NCV between the medicine group and placebo group 2) Conclusion of scoring of peripheral neuropathy

**Timepoint**

Just before starting chemotherapy, 3 months after starting chemotherapy, 6 months later and 1 year later, EMG\_NCV and scoring of peripheral neuropathy will be taken from the patients.

**Method of measurement**

Electro Myography\_Nerve Cunduction Velocity

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: Patients in this group will receive 300

mg tablet of lithium, one day before every chemotherapy cycle up to 5 days, each day one tablet.( 5 tablets in each cycle)

**Category**

Prevention

**2****Description**

Control group: Patients in this group will receive placebo one day before every chemotherapy cycle up to 5 days, each day one tablet.( 5 tablets in each cycle)

**Category**

Placebo

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Breast Cancer Rsearch Center

**Full name of responsible person**

Dr Safa Najafi

**Street address**

No 45, Vahid Nazari Street, Felestin Street, Enghelab Street

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131568591

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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Zahra Heidarali

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No. 99, Islamic Azad University of Pharmaceutical Science, Yakhchal St, Gholhak Area, Shariati Ave

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sahar.heidarali@gmail.com

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

**Title of funding source**

Main researcher: Zahra Heidarali

**Proportion provided by this source**

100

**Public or private sector**

Private

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

empty

**Country of origin****Type of organization providing the funding**

Persons

**Person responsible for general inquiries****Contact****Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Dr Mehdi Rajabi

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Pharmacy

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Iranian academic center for education culture and research

**Full name of responsible person**

Dr Safa Najafi

**Position**

Lecturer

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Oncologist and Hematologist

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Islamic Azad University  
**Full name of responsible person**  
Zahra Heidarali  
**Position**  
Student  
**Latest degree**  
A Level or less  
**Other areas of specialty/work**  
Medical Pharmacy  
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**Postal code**

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

### Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

### Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

### Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

### Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

### Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

### Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available