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 Platinium base medicines

Protocol summary

Study aim
Determination of lithium effectiveness in prevention of peripheral neuropathy in breast cancer patients under treatment with Taxans and Platinium 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 Teharan Islamic Azad University of Pharmaceutical scienses
Street address
No 99, Yakhchal Street, Gholhak Area, Shariati Ave
City
Tehran
Province
Tehran
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

City

Tehran

Province

Tehran

Postal code

131568591

Email

safa3n@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Zahra Heidarali

Street address

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

City

Tehran

Province

Tehran

Postal code

19395-6466

Email

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

Street address

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

City

Tehran

Province

Tehran

Postal code

19395-6466

Phone

+98 21 6393 5258

Email

mehdirj@aol.co.uk

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

Street address

#1, No. 15, Pardis Bldg, Pardis st, Mollasadra Ave, Vanak Sq

City

Tehran

Province

Tehran

Postal code
1991943491
Phone
+98 21 8879 8528
Email
safa3n@yahoo.com

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
Street address
No. 99, Islamic Azad University of Parmaceutical Science, Yakhchal St, Gholhak Area, Shariati Ave
City
Tehran
Province
Tehran
Postal code
19395-6466
Phone
+98 21 6393 5258
Email
sahar.heidarali@gmail.com

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