A double-blind, randomized, placebo-controlled multicenter study to investigate efficacy and safety of elinzanetant for the treatment of vasomotor symptoms over 26 weeks in postmenopausal women

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Assessment of the treatment of vasomotor symptoms during 26 weeks in postmenopausal women. In addition, there will be checked if improvement is noticed in sleep quality, menopausal related quality of life and depressive symptoms.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON54109

Source
ToetsingOnline

Brief title
Oasis-1

Condition

- Other condition

Synonym
Hot flushes, menopausal symptoms

Health condition

vasomotorische symptomen in de menopauze

Research involving
Human

Sponsors and support

Primary sponsor: Bayer
Source(s) of monetary or material Support: Bayer AG

Intervention

Keyword: elinzanetant, postmenopausal women, vasomotor symptoms

Outcome measures

Primary outcome

Mean change in frequency of moderate to severe hot flash (HF) from baseline to Week 4 (assessed by hot flash daily diary [HFDD])

Mean change in frequency of moderate to severe HF from baseline to Week 12 (assessed by HFDD)

Mean change in severity of moderate to severe HF from baseline to Week 4 (assessed by HFDD)

Mean change in severity of moderate to severe HF from baseline to Week 12 (assessed by HFDD)

Secondary outcome

Mean change in frequency of moderate to severe HF from baseline to Week 1 (assessed by HFDD)

Mean change in frequency of moderate to severe HF from baseline over time

Mean change in patient-reported outcomes measurement information system sleep disturbance short form 8b (PROMIS SD SF 8b) total score from baseline to Week 12

Mean change in menopause specific quality of life scale (MENQOL) total score

from baseline to Week 12

Mean change in Beck depression inventory (BDI-II) total score from baseline to

Week 12

Mean change in BDI-II total score from baseline to Week 26

Study description

Background summary

Researchers are looking for a better way to treat women who have hot flashes after they have been through the menopause. Hot flashes are caused by the hormonal changes that happen when a woman*s body has been through the menopause. Menopause is when women stop having a menstrual cycle, also called a period. During the period, the ovaries increasingly produce less sex hormones as a result of the natural ageing process and related hormonal adjustments. The decline in hormone production can lead to various symptoms which, in some cases, can have a very adverse effect on a menopausal woman's quality of life. The study treatment, BAY 3427080, was designed to treat symptoms caused by hormonal changes. It works by blocking a protein called neurokinin from sending signals to other parts of the body, which is thought to play a role in starting hot flashes. There are treatments for hot flashes in women who have been through the menopause, but may cause medical problems for some people. In this study, the researchers will learn how well BAY 3427080 works compared to a placebo in women who have been through the menopause and have hot flashes. A placebo looks like a treatment but does not have any medicine in it. To compare these study treatments, the doctors will ask the participants to record information about their hot flashes in an electronic diary. The researchers will study the number of hot flashes the participants have and how severe they are. They will look at the results from before treatment, after 4 weeks, and after 12 weeks of treatment.

Study objective

Assessment of the treatment of vasomotor symptoms during 26 weeks in postmenopausal women. In addition, there will be checked if improvement is noticed in sleep quality, menopausal related quality of life and depressive symptoms.

Study design

A double-blind, randomized, placebo-controlled multicenter study to investigate

efficacy and safety of elinzanetant for the treatment of vasomotor symptoms over 26 weeks in postmenopausal women.

Study duration: about 30 weeks
Screening Period: 2-4 weeks (plus washout period if applicable)
Treatment duration: 26 weeks
Follow-up period for safety

Intervention

Experimental: BAY 3427080, 120 mg daily oral administration as tablet.
Placebo: Placebo daily, placebo match for BAY 3427080 oral administration as tablet.

After randomization, each participant will receive BAY 3427080 or placebo orally daily for 12 weeks followed by a 14 week period during which both groups (BAY 3427080 and placebo group) will receive BAY 3427080 orally daily as tablet.

Study burden and risks

NA

Contacts

Public
Bayer

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NL
Scientific
Bayer

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Postmenopausal, defined as:
a. at least 12 months of spontaneous amenorrhea prior to signing of informed consent, or
b. at least 6 months of spontaneous amenorrhea prior to signing of informed consent with serum follicle-stimulating hormone (FSH) levels > 40 mIU/mL and a serum estradiol concentration of < 30 pg/mL, or
c. at least 6 months after hysterectomy at signing of informed consent with serum FSH levels > 40 mIU/mL and a serum estradiol concentration of < 30 pg/mL, or
d. surgical bilateral oophorectomy with or without hysterectomy at least 6 weeks prior to signing of informed consent.
- Moderate to severe hot flash (HF) associated with the menopause and seeking treatment for this condition.
- Participant has completed Hot Flash Daily Diary (HFDD) for at least 11 days during the two weeks preceding baseline visit, and participant has recorded at least 50 moderate or severe HF (including night-time HF) over the last 7 days that the HFDD was completed (assessed at the Baseline Visit)

Exclusion criteria

- Any clinically significant prior or ongoing history of arrhythmias, heart block and QT prolongation either determined through clinical history or on ECG evaluation.
- Any active ongoing condition that could cause difficulty in interpreting vasomotor symptoms (VMS) such as: infection that could cause pyrexia, pheochromocytoma, carcinoid syndrome.
- Current or previous history of any malignancy (except basal and squamous cell skin tumors).
- Uncontrolled or treatment-resistant hypertension. Women with mild hypertension can be included in the study if they are medically cleared prior to study participation.
- A history of untreated hyperthyroidism or hypothyroidism. Treated

hypothyroidism with normal thyroid function test results during screening and a stable (for >= 3 months before signing of informed consent) dose of replacement therapy is acceptable.
- Any unexplained post-menopausal bleeding.
- Clinically relevant abnormal findings on mammogram.
- Abnormal liver parameters.
- Disordered proliferative endometrium, endometrial hyperplasia, polyp, or endometrial cancer diagnosed based on endometrial biopsy during screening.

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-05-2022
Enrollment:	22
Type:	Actual

Ethics review

Approved WMO

Date:	04-10-2021
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO

Date:	02-12-2021
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	16-12-2021
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	23-12-2021
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	21-02-2022
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	14-03-2022
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	22-04-2022
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	28-04-2022
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	21-07-2022
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United

	(Nieuwegein)
Approved WMO Date:	22-07-2022
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	08-10-2022
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	19-10-2022
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	28-01-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	02-02-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2020-004908-33-NL
CCMO	NL78392.100.21