A phase I, open label study to investigate the absorption, metabolism and excretion of 14C-ESN-364 in healthy menopausal female volunteers.

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

Summary

ID

NL-OMON46563

Source
ToetsingOnline

Brief title
14C-ESN-364 ADME Study

Condition

- Other condition

Synonym
sex-hormone-related disorders

Health condition

geslachtshormoon gerelateerde aandoeningen

Research involving

Human

Sponsors and support

Primary sponsor: Ogeda
Source(s) of monetary or material Support: Farmaceutische Industrie.

Intervention

Keyword: 14C-ESN-364, sex-hormone-related disorders

Outcome measures

Primary outcome

To evaluate the pharmacokinetics (PK) of ESN-364 and total radioactivity, in particular, absorption, rates and routes of excretion and extent of metabolism of ESN-364, following administration of a single dose of 14C labeled ESN-364

To determine the mass balance of total radioactivity

Secondary outcome

To evaluate the PK of ES259564, the major metabolite, following administration of a single oral dose of 14C-labeled ESN-364

To evaluate the safety of single oral dose administration of ESN-364 in healthy volunteers

To identify the metabolic profile of ESN-364 in plasma, urine and feces after a single oral dose of 14C labeled ESN-364

Study description

Background summary

ESN364 is a new compound that may eventually be used for the treatment of sex-hormone-related disorders, for example, endometriosis, polycystic ovary syndrome, uterine fibroids, and menopausal hot flashes. ESN364 is a so-called NK3 receptor antagonist, a small molecule that blocks the NK3 receptor. By blocking the NK3 receptor, it is able to modulate hormone glands, including the hypothalamus, pituitary glands, and gonadal glands. As a result - at least in premenopausal women - the production of the ovarian hormones estrogen and progesterone will be altered. In the menopause, the effect of ESN364 will be mediated through a decreased activity of the NK3 receptor, ameliorating the occurrence of menopausal symptoms (hot flashes).

Study objective

In this study, it will be investigated how quickly and to what extent ESN364 is absorbed, processed by and eliminated from the body (this is called pharmacokinetics). ESN364 will be labelled with 14 Carbon (14C) and is thus radioactive. In this way ESN364 can be traced in blood, urine and feces.

It is also investigated how safe the new compound ESN364 is when it is administered to healthy subjects.

Study design

A total of 180 mg ESN364 will be given as an oral solution with a volume of 5 milliliter (mL) and with 240 mL of (tap) water.

When ESN364 is administered, the volunteers should have fasted for at least 10 hours (no eating and drinking). Also after administration of the study compound, they will be required to fast for 4 additional hours. Then they will be served lunch. During fasting they are allowed to drink water, exception during 1 hour before and 1 hour after administration of the study compound.

Day 1 is the day of administration of the study compound. The volunteers are expected at the research center at 14:00 h in the afternoon prior to the day of administration of the study compound.

The participation in the entire study depends on the amount of radioactivity measured in the blood, feces and urine. If, from Day 8 onwards, the radioactivity levels in urine and feces are below the pre-defined levels, the volunteers will be allowed to leave the research center. At the latest they will be allowed to leave the research center on Day 11 regardless of the amount

of radioactivity levels still present in the urine and feces. If on Day 11 the radioactivity levels in urine and feces are still not below the pre-defined levels, they will be asked to collect urine and feces at home during 2 x 24 hours (Days 11-12 and Days 12-13), that they will have to bring to the clinic on Day 13. If, from Day 13 onwards, the radioactivity levels in urine and feces are still not below the pre-defined levels, they will have to return to the clinic in the afternoon of Day 19 and Day 26 and they will leave the clinic after collection of urine and feces for 24 hours (Day 20 and Day 27).

Intervention

not applicable.

Study burden and risks

Pain, minor bleedings, bruises, possibly an infection.

Contacts

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Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

healthy female menopausal subjects
40-75 years, inclusive,
BMI 18.0-30.0 kg/m2, inclusive
50.0-100.0 kg, inclusive

Exclusion criteria

Suffering from hepatitis B, hepatitis C, cancer or HIV/AIDS. In case of participation in another drug study within 90 days before the start of this study or being a blood donor within 60 days from the start of the study. In case of donating more than 1.5 liters of blood in the 10 months prior the start of this study.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-03-2018
Enrollment:	6
Type:	Actual

Ethics review

Approved WMO Date:	20-02-2018
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	27-02-2018
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

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	EUCTR2017-004911-38-NL
CCMO	NL64904.056.18