Study of Females Exposed to Eleclazine

Published: 22-12-2022
Last updated: 06-04-2024

The objective of this study is to follow up with females exposed to eleclazine in prior clinical trials.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Reproductive neoplasms female malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON56367

Source
ToetsingOnline

Brief title
Eleclazine Safety Follow up study

Condition

- Reproductive neoplasms female malignant and unspecified

Synonym
uterine cancer, uterine carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Gilead Sciences, Inc.
Source(s) of monetary or material Support: industry;Gilead Sciences

Intervention

Keyword: cancer, eleclazine, uterine

Outcome measures

Primary outcome

The endpoints of interest include the number of females enrolled and the number

of females with signs or symptoms potentially consistent with uterine cancer

after eleclazine exposure.

Secondary outcome

none

Study description

Background summary

In 2016, Gilead Sciences, Inc. (Gilead) discontinued the development of Eleclazine because Eleclazine failed to meet the primary endpoint (due to lack of efficacy) in Study GS-US-356-0101.
Gilead Sciences issued safety notification letter in December 2017 regarding findings from the eleclazine nonclinical 2-year rat carcinogenicity study TX-279-2032.
These findings were shared with health authorities and Eleclazine investigators in December 2017 via a 15 day Safety Notification Letter. During 2018 feedback from FDA suggested a patient notification and follow-up of all subjects, BfArM suggested follow-up of females.
Gilead have designed a Follow up Study GS-US 356-5413 for Females who received at least one dose of Eleclazine in a prior Eleclazine clinical trial. This Follow up Study (GS-US-356-5413) is a multi-center Study which will be conducted in up to 11 countries, at approximately 57 sites that enrolled female subjects in prior Eleclazine clinical trials.

Study objective

The objective of this study is to follow up with females exposed to eleclazine in prior clinical trials.

Study design

This is a multi-center study. Sites that enrolled female subjects in prior

eleclazine clinical trials will be requested to participate in the study.

Study burden and risks

No experimental treatment will be administered in this study. The intervention is limited to a study visit/video call with the investigator and referral for a gynaecological evaluation. The possible risks of taking part in this study are associated only with these visits and gynaecological examination procedures.

Contacts

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Gilead Sciences, Inc.

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Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

1. Females who received at least one dose of eleclazine in a prior clinical trial

2. Signed informed consent form (ICF), by the subject or a legally authorized representative,
obtained before any study-related activities are undertaken

Exclusion criteria

none

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-09-2023
Enrollment:	4
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	22-12-2022
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO

Date:	11-05-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	26-05-2023
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	15-11-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	05-12-2023
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	EUCTR2019-003958-86-NL
CCMO	NL81118.100.22