An open-label, single arm, prospective, multi-center, tandem two stage designed, phase II study to evaluate the efficacy of Fulvestrant in women with recurrent/metastatic estrogen receptor positive gynecological malignancies

Published: 15-04-2019
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Evaluate the efficacy of the ER-antagonist Fulvestrant in women with estrogen receptor positive (ER+) low grade gynecological cancers

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Reproductive neoplasms female malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON50189

Source
ToetsingOnline

Brief title
FUCHSia

Condition

- Reproductive neoplasms female malignant and unspecified

Synonym
low grade gynacological tumors

Research involving
Human

Sponsors and support

Primary sponsor: UZ Leuven
Source(s) of monetary or material Support: Astra Zeneca,UZ Leuven

Intervention

Keyword: estrogen receptor postive, gynaecological malignancies, hormone therapy

Outcome measures

Primary outcome

To determine the response rate (RR) upon Fulvestrant treatment, comprising

either partial or complete response, as determined by RECIST v1.1 criteria, in

each tumor type group

Secondary outcome

• To determine progression-free survival (PFS) upon Fulvestrant treatment,

after 3 years, in each tumor type group

• To assess duration of response in each tumor type group

• To assess safety and tolerability of Fulvestrant administration in each tumor

type group

• To assess quality of life (QoL) and symptoms in each tumor type group

Study description

Background summary

Many gynecological malignancies are characterized by estrogen receptor (ER) expression, including low grade uterine sarcomas (LG-US), low grade endometrial carcinomas (LG-EC), sex cord stromal tumors and low grade epithelial serous ovarian cancers (LG-SC). Although several reports suggest that endocrine therapy can be effective in such gynecological cancers, because of their rare nature, there is still no consensus reached on the criteria needed to clearly define which population of patients would specifically benefit from anti-ER

treatment

Study objective

Evaluate the efficacy of the ER-antagonist Fulvestrant in women with estrogen receptor positive (ER+) low grade gynecological cancers

Study design

Single arm, prospective, multi-center, tandem two-stage designed phase II study, grouped by tumor type

Intervention

Fulvestrant intramuscular injection (2x 250mg), once every 2 weeks for the first month, and then monthly until completion of the study

Study burden and risks

The hypothesis is that Fulvestrant will show clinical efficacy in these patients with low-grade gynecological tumors that are resistant to other hormonal therapies and thus constitutes a new option for these patients before moving to cytotoxic therapy. The risks for the patient are drug-related side effects, but in general the safety profile of Fulvestrant is favorable. Weighed against the possible advantage of having a clinical response, the risk-benefit analysis according to the investigators is positive.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Written informed consent prior admission to the study
Age >= 18 years at the moment of signing the informed consent
Recurrent or metastatic low grade uterine sarcomas, low-grade endometrial carcinomas, sex cord stromal tumors and low grade serous ovarian cancer
Measurable disease, according to RECIST v1.1 criteria
ER-positive tumors based on immunohistochemistry, more than 10% of tumor cells should be positive for ER. After the study, central analysis of ER staining will be assessed using the Allred scoring system (based on intensity and percentage of positive cells) and archival tissue (< 3 years old) available
1 or 2 prior lines of hormonal therapy
ECOG performance status: 0-2
Demonstrate adequate organ function
Post-menopausal status
Be willing to receive 18F-FES PET scan.

Exclusion criteria

• Any other active malignancy or primary malignancy diagnosed within the previous 5 years, except for adequately treated squamous or basal cell carcinoma of the skin or in situ cervical carcinoma
• Patients currently receiving (and unwilling to discontinue) any estrogen replacement therapy.
• Patients participating in a study or having participated in a study of an investigational agent and received study therapy (or used an investigational device) within 4 weeks prior to study Day 1
• Patients who received prior chemo- or targeted therapy within 4 weeks prior to study Day 1 or who has not recovered from adverse events (i.e., adverse

event not resolved to <= Grade 1 or baseline), due to a previously administered agent
• Patients with no archival tissue available, except for patients from whom an additional fresh core biopsy can be obtained for ER assessment
• Any other disease, metabolic dysfunction, physical examination or clinical laboratory finding that, in the investigator's opinion, gives reasonable suspicion of a disease or condition that contraindicates the use of an investigational drug, may affect the interpretation of the results, render the patient at high risk from treatment complications or interfere with obtaining informed consent.
• Any condition not permitting compliance with the study protocol

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	27-06-2019
Enrollment:	80
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Faslodex
Generic name:	fulvestrant
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	15-04-2019
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	12-06-2019
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	29-05-2020
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	19-06-2020
Application type:	Amendment
Review commission:	METC NedMec

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	EUCTR2017-005018-76-NL
ClinicalTrials.gov	NCTnummervolgt
CCMO	NL65737.031.18