A PHASE III RANDOMIZED TRIAL OF GEMCITABINE PLUS DOCETAXEL FOLLOWED BY DOXORUBICIN V. OBSERVATION FOR UTERUS-LIMITED, HIGH GRADE UTERINE LEIOMYOSARCOMA

Published: 11-11-2014
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To improve overall survival of patients with a early-stage high grade uterine leiomyosarcoma.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Reproductive neoplasms male malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON41992

Source
ToetsingOnline

Brief title
EORTC 55116-62114

Condition

- Reproductive neoplasms male malignant and unspecified

Synonym
leiomyosarcoma, uterine

Research involving
Human

Sponsors and support

Primary sponsor: European Organisation for Research in Treatment of Cancer (EORTC)

Source(s) of monetary or material Support: EORTC

Intervention

Keyword: adjuvant, chemotherapy, leiomyosarcoma, uterine

Outcome measures

Primary outcome

To determine whether overall survival of patients with uterus-limited high-grade leiomyosarcoma is superior among patients assigned to treatment with adjuvant gemcitabine plus docetaxel followed by doxorubicin compared to patients assigned to observation.

Secondary outcome

To determine whether treatment with adjuvant gemcitabine plus docetaxel followed by doxorubicin improves recurrence-free survival of patients with uterus-limited high-grade leiomyosarcoma compared to observation.

To explore the impact of potential predictors of recurrence or death such as patient age, and institution reported tumor size, cervix involvement (yes or no), and mitotic rate.

Study description

Background summary

Patients with early-stage, high-grade uterine leiomyosarcoma (LMS) have a 50-70% chance of relapse/recurrence of disease. Recurrences may be distant or local or both. In one GOG study of prognostic factors for recurrence of LMS, only 14% of patients with stage I or II disease had isolated pelvic recurrences as

the
site of first recurrence. Adjuvant pelvic radiation can decrease local recurrence
rates, but has not been shown to increase overall survival. In the EORTC randomized trial of adjuvant whole pelvic radiation v. observation for FIGO stage
I and II uterine sarcomas, the recurrence rates were approximately 50% in both arms of the study. The percentage of leiomyosarcoma patients remaining progression-free at 2 years in that study was approximately 58%, and the percentage of all patients (both uterine LMS and uterine carcinosarcoma) that remained progression-free at 3 years was 52%.
A recent prospective phase II study of adjuvant gemcitabine plus docetaxel followed by doxorubicin for women with uterus-limited high-grade LMS was conducted by the Sarcoma Alliance for Research through Collaboration (SARC) and the results were presented at the American Society of Clinical Oncology (Hensley, ASCO 2010). In that study (SARC005), 47 women with uterus-limited high-grade LMS were enrolled over 3 years' time. All patients were treated with adjuvant gemcitabine + docetaxel for four cycles. Provided that repeat CT imaging showed no evidence of disease, patients then received four cycles of doxorubicin. All patients were followed with CT imaging every 3 months for 2 years, then every 6 months for 3 years.

Study objective

To improve overall survival of patients with a early-stage high grade uterine leiomyosarcoma.

Study design

Enroll Patients with
1) High-grade uterine LMS
2) FIGO Stage I (uterus +/- cervix)
Hysterectomy +/- BSO
Randomize of the patient
Regimen 1: gemcitabine on day 1 and 8
Docetaxel on day 8
GCSF on day 9-15 or pegfilgrastim on day 9 and 10
Every 21 days for 4 cycles
CT/MRI imaging to confirm disease-free
Doxorubicin 60 mg/m2 IV every 21 days for 4 cycles

regime 2
observation

Intervention

-in ona study arm patients will recieve a maximum of 8 courses of chmeotherapy
(4 courses gemcitabine/docetaxel) and 4 courses doxorubicine.

Study burden and risks

Side effects of the chemotherapy

Contacts

Public
European Organisation for Research in Treatment of Cancer (EORTC)

Avenue Emanual Mounier 83/11
Brussel 1200
BE
Scientific
European Organisation for Research in Treatment of Cancer (EORTC)

Avenue Emanual Mounier 83/11
Brussel 1200
BE

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients with a high risk of uterine leiomyosarcoma FIGO stage I.
Institutional pathology review of leiomyosarcoma
Al patients must be no longer than 12 weeks (3 months) from surgical resection of cancer at

the time of enrollment on study.
Age > 18 years
Written informed consent

Exclusion criteria

Patient who had prior therapy with docetaxel or gemcitabine or doxorubicine
Patient with a history of malignancy being present within the last 5 years
Patient with a history of severe hypersensitivity reaction to anthracenedione/anthracyclines or drugs containing polysorbate 80 excipients are not allowed to participate in the study.

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	18
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	doxorubicine
Generic name:	doxorubicine
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Gemcitabine hydrochloride

Generic name:	gemcitabine
Product type:	Medicine
Brand name:	taxotere
Generic name:	docetaxel
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	11-11-2014
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	13-07-2015
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	16-10-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	24-12-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	EUCTR2012-002852-17-NL
ClinicalTrials.gov	NCT01533207
CCMO	NL48441.042.14