Therapy De-escalation in Seminoma Stage IIA/B

This study is currently recruiting participants. (see Contacts and Locations)

Verified May 2015 by Swiss Group for Clinical Cancer Research

Sponsor:
Swiss Group for Clinical Cancer Research

Information provided by (Responsible Party):
Swiss Group for Clinical Cancer Research

ClinicalTrials.gov Identifier:
NCT01593241

First received: May 1, 2012
Last updated: May 15, 2015
Last verified: May 2015
History of Changes

Purpose

The main objective of this trial is to test the efficacy and safety of carboplatin chemotherapy and involved node radiotherapy in patients with stage IIA/B seminoma.

Condition	Intervention	Phase
Seminoma	Drug: Carboplatin Radiation: Involved node RT	Phase 2

Study Type: Interventional
Study Design: Endpoint Classification: Safety/Efficacy Study
Intervention Model: Single Group Assignment
Masking: Open Label
Primary Purpose: Treatment

Official Title: Carboplatin Chemotherapy and Involved Node Radiotherapy in Stage IIA/B Seminoma

Resource links provided by NLM:

Drug Information available for: Carboplatin

Genetic and Rare Diseases Information Center resources: Seminoma

U.S. FDA Resources

Further study details as provided by Swiss Group for Clinical Cancer Research:

Primary Outcome Measures:

- Progression free survival (PFS) [Time Frame: at 3 years (± 1 month)] [Designated as safety issue: No]
  success/failure of PFS

Secondary Outcome Measures:

- Adverse events (AEs) temporarily associated with the trial treatment [Time Frame: at 3 years] [Designated as safety issue: Yes]
  AEs are collected from inclusion until 30 days after the end of treatment

- Late AEs [Time Frame: at the latest at 20 years] [Designated as safety issue: Yes]

AEs will be collected from 30 days after the end of treatment until the end of the follow-up phase

- Incidence of secondary malignancies [Time Frame: at the latest at 20 years] [Designated as safety issue: Yes]
- Response rate [Time Frame: at 3 years] [Designated as safety issue: No]
- Time to progression (TTP) [Time Frame: at the latest at 20 years] [Designated as safety issue: No]
  from registration until documented progressive disease, relapse or death due to tumor.
- Overall survival (OS) [Time Frame: at the latest at 20 years.] [Designated as safety issue: No]
  from registration to the date of death from any cause
- Seminoma specific survival [Time Frame: at the latest at 20 years] [Designated as safety issue: No]
  from registration to the date of death due to seminoma
- PFS [Time Frame: at the latest at 20 years] [Designated as safety issue: No]
  from registration to the date of failure of PFS
- Localization of progression [Time Frame: at the latest at 20 years] [Designated as safety issue: No]
  from first localization where recurrent tumor disease is detected

Estimated Enrollment:	115
Study Start Date:	May 2012
Estimated Study Completion Date:	June 2037
Estimated Primary Completion Date:	October 2017 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Carboplatin	Drug: Carboplatin Stage IIA: 1 infusion Carboplatin AUC7 followed by 15 x 2 Gy involved node radiotherapy Stage IIB: 1 infusion Carboplatin AUC7 followed by 18 x 2 Gy involved node radiotherapy Radiation: Involved node RT Involved node RT

Show Detailed Description

Eligibility

Ages Eligible for Study:	18 Years and older
Genders Eligible for Study:	Male
Accepts Healthy Volunteers:	No

Criteria
Inclusion Criteria:

- Patient has given written informed consent before registration.
- Histologically confirmed classical seminoma treated with primary inguinal orchidectomy.
- Tumor stage at diagnosis or at relapse after primary active surveillance is pT1-4* cN1-2 cM0 according to UICC TNM 2009 is pT1-4 cN1-2 cM0 according to UICC TNM 2009.
- Multi-slice CT of the chest, abdomen and pelvis or a FDG-PET-CT within 4 weeks prior to patient registration, showing stage IIA/B disease. Oral and i.v. contrast have to be administered.
- Age ≥ 18 years.
- WHO performance status 0-2.
- Adequate hematological values: neutrophils ≥ 1.0 x 109/L, platelets ≥ 100x 109/L.
- Adequate renal function (calculated creatinine clearance ≥ 50 ml/min, according to the formula of Cockcroft-Gault).
- Patient agrees not to father a child during trial treatment and during 12 months thereafter.
- Patient has been proposed sperm conservation.
- Patient compliance and geographic proximity allow proper staging and follow-up for at least 3 years.

Exclusion Criteria:

- Previous or concurrent malignancy within 5 years with the exception of localized non-melanoma skin cancer or stage I seminoma for patients entering the trial with relapse during active surveillance.
- Psychiatric disorder precluding understanding of information on trial-related topics or giving informed consent or interfering with compliance for treatment schedule.
- Mixed histology seminoma.
- Elevated levels of AFP (≥ULN) at any time.
- Any prior abdominal/pelvic radiotherapy (RT).
- Any anti-cancer therapy after primary tumor resection (active surveillance for stage I disease is not considered as a treatment).
- Any treatment in a clinical trial within 30 days of trial entry.
- Any serious underlying medical condition or serious co-morbidity (at the judgment of the investigator) which could impair the ability of the patient to participate in the trial.
- Any contraindication for the trial drug (for example, known hypersensitivity to trial drug or to any other co-component of the trial drug, past or current renal insufficiency, severe hepatic insufficiency, severe bone marrow dysfunction, tumor bleeding, major hearing defects).
- Any concomitant drugs contraindicated for use with the trial drug according to the approved product information (for example, nephrotoxic or ototoxic medicines).

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT01593241

Contacts

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Locations

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More Information

Additional Information:

Related Info

No publications provided

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Seminoma IIA/B
Carboplatin
RT

Additional relevant MeSH terms:

Seminoma
Germinoma
Neoplasms
Neoplasms by Histologic Type
Neoplasms, Germ Cell and Embryonal

Carboplatin
Antineoplastic Agents
Pharmacologic Actions
Therapeutic Uses

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