A phase II study in mCRPC on the pharmacodynamic effects of budesonide on cabazitaxel (Jevtana®): A randomised, open-label multicenter study: CABARESC

Published: 02-08-2011
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Primary objective: To study the effects of budesonide on the incidence of cabazitaxel induced diarrhea Secondary objectives: To study the effects of budesonide on other side effects of cabazitaxel (e.g. myelotoxicity), To study the pharmacogenetics...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Reproductive neoplasms male malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON41486

Source
ToetsingOnline

Brief title
CABARESC

Condition

- Reproductive neoplasms male malignant and unspecified

Synonym
metastatic castrate resistant prostate cancer

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: Ministerie van OC&W,sanofi-aventis

Intervention

Keyword: budesonide, cabazitaxel, diarrhea, prostate cancer

Outcome measures

Primary outcome

Incidence of cabazitaxel-induced diarrhea.

Secondary outcome

Incidence of other side effects of cabazitaxel. Pharmacogenetics of

cabazitaxel.

Study description

Background summary

Cabazitaxel is a new drug to be used for the treatment of metastatic castrate resistant prostate cancer after progression on docetaxel therapy. Unfortunately, a relatively high incidence of diarrhea (50%, mainly during the 1st two cycles, median onset after 7 days of therapy) is limiting its dose/use. The aim of this study is to assess the prophylactic effect of budesonide on cabazitaxel induced diarrhea. The hypothesis is that the local anti-inflammatory effects of budesonide will have a favorable effect on the incidence of diarrhea in cabazitaxel treatment. In a previous pharmacokinetic safety study no clear interaction between cabazitaxel and budesonide was shown.

Study objective

Primary objective: To study the effects of budesonide on the incidence of cabazitaxel induced diarrhea
Secondary objectives: To study the effects of budesonide on other side effects of cabazitaxel (e.g. myelotoxicity), To study the pharmacogenetics of cabazitaxel.

Study design

Multicenter randomized open phase II parallel group study.
Patient will be randomly allocated to either:

• Budesonide 9 mg daily starting 2 days prior to cycle 1 until 2 weeks, for a maximum of 44 consecutive days.
• No budesonide.
All patiënts will be treated with cabazitaxel 25 mg/m2 via i.v. infusion of approx. 1 h, once every 3 weeks. Max. 10 cycles. No dose capping. Premature discontinuation in case of disease progression or unacceptable toxocity.
250 patients to be included.
Interim-analysis (safety) after 50 % inclusion.
Substudies:
- counting and characterization of circulating tumor cells.
- development of a biomarker prophyle for future prediction of positive response to cabazitaxel.

Intervention

Treatment with or without budesonide.

Study burden and risks

Risk: adverse events of study medication.
Burden:
Visits, investigations similar to standard treatment with cabazitaxel.
Diary (diarrhea) from 7 days prior to 1st cycle until start 3rd cycle.
Optional blood draw for pharmacogenetic research (20 ml) and research for circulating tumor cells (20 ml). Rest: storage for future research.
Substudy circulating tumor cells(optional): 20 ml. blood on 2 occasions.
Substudy biomarker prophyle (optional): 2x tumor biopsy.

Contacts

Public
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

• Metastatic castrate resistant prostate cancer patients with documented disease progression (Resist criteria (measurable disease) or PSA (non-measurable disease))
• Previous treatment with a docetaxel-containing regimen
• Age 18 years and above
• WHO performance status 0-1
• Castration, either surgically or by continued LHRH agonist therapy.

Exclusion criteria

• CYP3A inducers or inhibitors
• Systemic or local bacterial, viral, fungal or yeast infection
• Portal hypertension (grade 1-4 CTC-NCI criteria)
• Ulcerative colitis, Crohn*s disease or celiac disease
• Simultaneous yellow fever vaccine.

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-12-2011
Enrollment:	270
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO Date:	02-08-2011
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	06-12-2011
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	13-02-2012
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	17-04-2012

Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	22-05-2012
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	29-11-2012
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	08-02-2013
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	10-04-2013
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	23-08-2013
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	05-12-2013
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	18-12-2013
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO Date:	27-02-2014
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	03-03-2014
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	28-08-2014
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	22-09-2014
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	19-08-2015
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	09-09-2015
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 27669
Source: NTR
Title:

In other registers

Register	ID
EudraCT	EUCTR2011-003346-40-NL
CCMO	NL37676.078.11
Other	www.trialregister.nl, registratienummer NTR2991