A Phase 3 Randomized, Double-Blind, Placebo-Controlled Study of Tasquinimod in Men with Metastatic Castrate-Resistant Prostate Cancer.

Published: 18-01-2011
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The primary objective of this study is:To confirm the effect of Tasquinimod on delaying disease progression or death compared with placebo.The secondary objectives of this study are:• To determine the effect of Tasquinimod on overall survival, time...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Metastases
Study type	Interventional

Summary

ID

NL-OMON41396

Source
ToetsingOnline

Brief title
10TASQ10

Condition

- Metastases
- Prostatic disorders (excl infections and inflammations)

Synonym
Metastatic Castrate-Resistant Prostate Cancer

Research involving
Human

Sponsors and support

Primary sponsor: Active Biotech
Source(s) of monetary or material Support: Industrie

Intervention

Keyword: Mildly symptomatic, Prostate Cancer, Tasquinimod

Outcome measures

Primary outcome

The primary endpoint is Progression-free survival defined as the time from the

date of randomization to the date of radiological progression or death.

Secondary outcome

The secondary endpoints are:

• OS

• Time to radiological progression

• Time to symptomatic progression (including death due to prostate cancer)

• Time to first radiological or symptomatic progression

• Time to first radiological or symptomatic progression or death (due to any

cause)

• Time to initiation of salvage systemic therapy, including chemotherapy, or

palliative radiation

• Time to new soft tissue lesion

- Time to progression due to soft tissue lesions (according

to RECIST 1.1)

- Time to skeletal-related events

• Time to new bone lesion

- Time to opiate use for cancer pain

• Quality of life measured by FACT P and EQ 5D questionnaire

• Changes in Karnofsky score

• Changes in VAS for tumor related pain

• Changes in serum PSA over time

• Changes in bone specific BAP over time

• Changes in vascular endothelial growth factor over time

• Population pharmacokinetics of tasquinimod

• Safety

• Time to radiological progression, overall survival, time to symptomatic

progression and quality of life

After the formal final statistical analysis, and upon request, the following

ancillary endpoints for the OLE/FUE phase of the study will be provided:

- Safety

- Initiation of new anticancer therapies

- Overall survival

Study description

Background summary

Wereldwijd is prostaatkanker de tweede meest voorkomende vorm van kanker bij mannen. Een derde van de patiënten die behandeld worden ervaren hierna een herhaling. Uiteindelijk kan de kanker zich tot gemetastaseerde, castratie-resistente prostaatkanker ontwikkelen.

Tasquinimod heeft een anti-angiogenische en tumorgroei remmende activiteit. Op het moment, waarbij de patiënt gemetastaseerde, castratie-resistente prostaatkanker heeft ontwikkeld en geen of milde symptomen heeft, bestaat met Tasquinimod, in vergelijking met chemotherapie, een behandeling, met weinig tot geen toxiciteit. Dit onderzoek is nodig om het effect van Tasquinimod op het vertragen van de ziekte progressie te bevestigen.

Study objective

The primary objective of this study is:
To confirm the effect of Tasquinimod on delaying disease progression or death compared with placebo.

The secondary objectives of this study are:
• To determine the effect of Tasquinimod on overall survival, time to symptomatic progression, additional radiological and clinical efficacy endpoints, quality of life parameters, and safety as compared with placebo.
• To assess the pharmacokinetics of Tasquinimod in men with metastatic CRPC.

Study design

A Phase 3 randomized, double blind, placebo controlled study.

Intervention

The treatment maintenance dose will be a maximum of 1 mg of Tasquinimod (or matching placebo) taken once daily.

Study burden and risks

Also, see Table 7-1 en Table 4-5 from Protocol:

5-6 x Physical Examination
10-12 x Vital Signs (body temperature, heart rate, blood pressure)
2 x ECG
5-6 x CT or MRI scans
6-7 x Bone scans
10-19 x Blood Sample
5 x FACT-P, EQ-5D, VAS

The most common side effects (10% or more) are:
Fatigue, nausea, abdominal discomfort or pain, arthralgia, headache, constipation.
Less common (from 5% to 9%):
Anemia, flatulence, diarrhea, vomiting, increased blood amylase, increase lipase, decreased appetite, back pain, myalgia, pain in extremity.

Quite rare (from 2% to 4%):
Insomnia, decreased weight, peripheral edema, musculoskeletal pain, inflammation, red blood cell sedimentation rate increase, muscular weakness, dizziness, lethargy, paraesthesia, bone pain, neck pain, blood fibrinogen increase, pain in limb, C-reactive protein increase.

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

2. Histologically confirmed diagnosis of adenocarcinoma of the prostate.
3. Evidence of bone metastatic disease on radiographic examination, whether from bone scan (bone lesions) or other imaging modality.
4. Castrate levels of serum testosterone (<=50 ng/dL or 1.7 nmol/L).
5. Evidence of progressive disease after castration levels of testosterone have been

achieved, defined by any of the following criteria:
• Increasing serum PSA levels, the most recent value >=2 ng/mL.
• Progression of soft tissue metastasis documented within 6 weeks of enrollment (computed tomography [CT] scan or magnetic resonance imaging [MRI])
• Progression of bone disease (at least 1 new bone lesion as measured by bone scan within the past 12 weeks)
6. Karnofsky score >=70%.
7. Laboratory values as follows:
• Hemoglobin >=100 g/L (>10 g/dL)
• Absolute neutrophil count >=1500/µL
• Platelets >=100 000/µL
• Serum creatinine <=1.5 times the upper limit of normal (ULN)
• Total bilirubin <=1.5 times ULN
• Aspartate aminotransferase and alanine aminotransferase <=3 times ULN
9. No evidence (within 5 years) of prior malignancies (except successfully treated basal cell or squamous cell carcinoma of the skin).;Inclusion criteria for the open-label extension treatment phase: In order to be enrolled in the OLE treatment phase, each patient must meet all of the OLE inclusion criteria. The open-label Day 1 visit should be at the planned patient visit following unblinding and within no more than 4 months after this amendment is approved and becomes effective at the study site.
1. Received tasquinimod or placebo treatment in the randomized doubleblind treatment phase of this study.
2. Willing and able to give informed consent for OLE treatment.
3. All of the safety related inclusion criteria for the main study, numbers 6 to 8 and 10 to 12.
4. No evidence (within 5 years) of prior malignancies (except successfully treated basal cell or squamous cell carcinoma of the skin) or, in case of occurrence of a cancer during the study, the option to switch to the OLE treatment phase will be done on a case-by-case basis taking into account the benefit/risk for the patient.

Exclusion criteria

1. Prior cytotoxic chemotherapy for the treatment of prostate cancer within 2 years.
2. Previous anticancer therapy using radiation, biologics or vaccines, including sipuleucel-T (Provenge), abiraterone, TAK-700 (Ortenel), or MDV3100 within 4 weeks prior to the start of study treatment. If radiation therapy is applied after baseline scan, a new baseline scan needs to be done at least 4 weeks after the radiation therapy.
3. Previous therapy with antiandrogens within 4 weeks (within 6 weeks for bicalutamide eg, Casodex®)
6. Prostate cancer pain that requires ongoing treatment with narcotic analgesics or warrants the initiation of radio -or chemotherapy..
15. Known brain or epidural metastases.
16. Known positive serology for HIV
17. Chronic hepatitis with advanced, decompensated hepatic disease or cirrhosis of the liver or history of a chronic viral hepatitis or known viral hepatitis carrier (patients who have recovered from hepatitis will be allowed to enter the study).

18. Patients with active tuberculosis (TB), or with known, untreated latent TB. ;Exclusion criteria for the open-label extension treatment phase: Patients meeting any of the following criteria will be excluded from being enrolled in the OLE treatment phase:
1. Having met any of the reasons for withdrawal from study treatment.
2. Having met any of the safety related exclusion criteria for the mainstudy, numbers 6 to 20.

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-11-2011
Enrollment:	35
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Tasquinimod
Generic name:	-

Ethics review

Approved WMO

Date:	18-01-2011
Application type:	First submission

Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	25-05-2011
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	19-07-2011
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	08-03-2012
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	17-04-2012
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	12-11-2012
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	23-08-2013
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	06-02-2015
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	10-02-2015
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	EUCTR2010-021870-12-NL
ClinicalTrials.gov	NCT01234311
CCMO	NL34582.091.11