

# A randomised study about the effect on survival of hormonal therapy versus hormonal therapy plus local external radiation therapy in patients with primary diagnosed metastasised (M+) prostate cancer

<b>Submission date</b> 20/12/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 20/12/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 11/10/2018	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

NTR271

## **Study information**

### **Scientific Title**

A randomised study about the effect on survival of hormonal therapy versus hormonal therapy plus local external radiation therapy in patients with primary diagnosed metastasised (M+) prostate cancer

### **Acronym**

HORRAD

### **Study objectives**

Today the standard therapy for patients primary diagnosed with M+ prostate cancer (bone metastasis) is systemic hormonal therapy. If standard hormonal treatment will be combined with local external radiation therapy of the prostate the survival may improve.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Received from the local medical ethics committee

### **Study design**

Multicentre randomised active-controlled parallel-group trial

### **Primary study design**

Interventional

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Hospital

### **Study type(s)**

Treatment

### **Participant information sheet**

### **Health condition(s) or problem(s) studied**

Prostate cancer

### **Interventions**

Group 1 will be hormonally treated with a LHRH analogue

Group 2 will be hormonally treated with a LHRH analogue in combination with local external radiation therapy of the prostate (70 Gray)

Joint sponsor:  
Erasmus Medical Centre (The Netherlands)  
Department of Urology  
P.O. Box 1738  
Rotterdam, 3000 RD  
The Netherlands

**Intervention Type**

Drug

**Phase**

Not Applicable

**Drug/device/biological/vaccine name(s)**

LHRH analogue

**Primary outcome measure**

Survival

**Secondary outcome measures**

1. Biochemical progression
2. Health-related quality of life

**Overall study start date**

01/11/2004

**Completion date**

01/07/2017

**Eligibility**

**Key inclusion criteria**

1. Histologically proven adenocarcinoma of the prostate
2. Stage T1-4, G1-3, N0-2, M1
3. Bone metastases diagnosed with a bonescan

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Male

**Target number of participants**

425

**Key exclusion criteria**

1. Start therapy more than 8 weeks after the initial diagnoses
2. Other treatment for prostate cancer before start of the study therapy
3. Other malignancies except skin carcinoma
4. Prostate specific antigen (PSA) less than 20 ng/ml
5. Aged greater than 80 years
6. Participation in another protocol
7. Not capable of filling out quality of life questionnaires

**Date of first enrolment**

27/11/2004

**Date of final enrolment**

04/09/2014

## **Locations**

**Countries of recruitment**

Netherlands

**Study participating centre**

**Onze Lieve Vrouwe Gasthuis (OLVG)**

Amsterdam

Netherlands

1090 HM

## **Sponsor information**

**Organisation**

Onze Lieve Vrouwe Gasthuis (OLVG) (The Netherlands)

**Sponsor details**

Department of Urology

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informatie@olv.nl

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.olvg.nl/>

**ROR**

<https://ror.org/01d02sf11>

## **Funder(s)**

**Funder type**

Industry

**Funder Name**

AstraZeneca (The Netherlands)

**Alternative Name(s)**

AstraZeneca PLC, Pearl Therapeutics

**Funding Body Type**

Government organisation

**Funding Body Subtype**

For-profit companies (industry)

**Location**

United Kingdom

**Funder Name**

Ipsen Fund

**Alternative Name(s)**

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Other non-profit organizations

**Location**

United Kingdom

## **Results and Publications**

**Publication and dissemination plan**

Planned publication in a high-impact peer reviewed journal.

**Intention to publish date**

01/06/2018

### Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date.

### IPD sharing plan summary

Data sharing statement to be made available at a later date

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	survival results	01/03/2019		Yes	No