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

Submission date	Recruitment status No longer recruiting	Prospectively registered		
20/12/2005		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
20/12/2005	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
11/10/2018	Cancer			

Plain English summary of protocolNot provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr G van Andel

Contact details

Onze Lieve Vrouwe Gasthuis (OLVG) Department of Urology P.O. Box 95500 Amsterdam Netherlands 1090 HM

g.v.andel@wxs.nl

Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

Survival

Key secondary outcome(s))

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Male

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)

ROR

https://ror.org/01d02sf11

Funder(s)

Funder type

Industry

Funder Name

AstraZeneca (The Netherlands)

Alternative Name(s)

AstraZeneca PLC, Pearl Therapeutics, AZ

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

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?
Results article	survival results	01/03/2019		Yes	No