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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	[_] Prospectively registered
20/12/2005	No longer recruiting	[_] 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 protocol
Not 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

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
P.O. Box 95500
Amsterdam
Netherlands
1090 HM
+31 (0)20 599 9111
informatie@olvg.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?
Results article	survival results	01/03/2019		Yes	No