Evaluation of the effect of psycho-oncological intervention on well-being of patients with advanced prostate cancer on LHRH analogs and their partners. A randomized controlled pilot study.

Published: 07-02-2012
Last updated: 01-05-2024

To asses the feasibility of conducting a larger trial to evaluate the effect of a psychological intervention on well-being of patients on LHRH analogs in the treatment of prostate cancer and their partners.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Miscellaneous and site unspecified neoplasms benign
Study type	Interventional

Summary

ID

NL-OMON39520

Source
ToetsingOnline

Brief title
EXPEDIENT

Condition

- Miscellaneous and site unspecified neoplasms benign
- Adjustment disorders (incl subtypes)

Synonym
coping / adaptation

Research involving
Human

Sponsors and support

Primary sponsor: Ipsen Pharmaceuticals
Source(s) of monetary or material Support: Ipsen Farmaceutica b.v.

Intervention

Keyword: prostate cancer, psychological intervention, quality of life, randomized clinical trial

Outcome measures

Primary outcome

Sufficiënt interest in participation, made clear by:

- Recruitment of 50 couples in 1,5 year in the participating centers

- 20% of couples that were informed personally about the study consent to

participate

- 80% of participants group 1 attends at least 70% of the sessions

Some indication for improvement in well-being

- - Group 1 should improve more than group 2 at at least one of the

- outcome measures (HADS, EORTC QLQ-C30 or

- Maudsley Marital Questionnaire) - after the intervention period of 16 weeks

(T1)

- - Group 1 should not worsen more than group 2 on any of the outcome

measures - after the intervention period of 16 weeks

(T1)

Secondary outcome

Depression and anxiety (patient) will be assessed with the Hospital Anxiety and

Depression Scale (HADS) at baseline (T0), after the intervention period of 16

weeks (T2) and at 1 year (T2).

EORTC QLQ-C30 (patient + partner) and QLQ-PR25 (patient) scores will be assessed at baseline (T0), after the intervention period of 16 weeks (T1) and at 1 year (T2). The HADS (partner) will be assessed at baseline (T0), after the intervention period of 16 weeks (T1) and at 1 year (T2) and the relationship satisfaction (patient and partner) with the Maudsley Marital Questionnaire at baseline (T0), after the intervention period of 16 weeks (T1) and at 1 year (T2). Distress meter (Lastmeter) will be assessed at baseline T0 (patient).
- difference between change in HADS scores at baseline (T0) and after the intervention period of 16 weeks (T1) between patients in group 1 and group 2.
- difference between change in QLQ-C30 scores at baseline (T0), after the intervention period of 16 weeks (T1) and at 1 year (T2) between patients and partners in group 1 and group 2
- difference between change in QLQ-PR25 scores at baseline (T0), after the intervention period of 16 weeks (T1) and at 1 year (T2) between patients in group 1 and group 2.
- difference in relationship satisfaction (Maudsley Marital Questionnaire) between baseline (T0), after the intervention period of 16 weeks (T1) and at 1 year (T2) in patients and partners group 1 and 2.
- difference between level of depression and anxiety (HADS) in patients and partners between baseline (T0) and at 1 year (T2) in group 1 and group 2
- The distress meter (lastmeter) will be used to describe the patient population

The following clinical and demographic data will be collected during (regular) urologist visits are used to describe the patient population:

- Date of birth

- Education level

- Date of diagnosis

- Use of LHRH-analogue

- Anti-androgen (type + posology)

- TNM classification if available. In case of M1, location and extent of lesions if any

- Gleason score (primary + secondary)

- Testosterone (in case pre-hormonal treatment testosterone is available, this will be documented)

- PSA

- Medical history

- Co-medication (e.g. analgesics)

- Co-morbidity (Charlson Index, decrease renal functioning)

- Co-intervention

- VAS (pain)

After the sessions the therapy will be evaluated by in-depth interviews with volunteers (group 1): couples or individuals in order to gain qualitative feedback on the therapy provided.
All participants will be asked after the intervention period of 16 weeks (T1) and at 1 year (T2) which, if any, additional therapy they have received for descriptive purposes.

Study description

Background summary

There is an increasing awareness for the patients need for psycho-oncological care in the Netherlands (introduction of distress meter in hospitals, providing additional care by oncology nurses). The Helen Dowling Institute aimes at providing psycho-oncological care by individual therapy, group counselling and on-lin therapy (fatigue - national coverage) to patients (Utrecht area) and their partners and family. In the past they have evaluated the quality of life of prostate cancer patients, but currently there is no (group) therapy specifically aimed at prostate cancer patients. As prostate cancer patients are still a diverse group of patients and because the side effects of hormonal therapy can have an influence on the life or patients and their partners, it was chosen to develop a group therapy (by means of information sessions) specifically aimed at this group of patients.
Next to impotence (which also frequently occurs in patients who are treated with curative intent), these patients also suffer from amongst others loss of libido, fatigue, change of body (more fat, less muscle mass), emotional instability as a consequence of the decrease of testosteron (below castration level). The purpose of the therapy is to learn how to deal with these aspects of the treatment and to improve the well-being and the partner relationship.

Before setting up a large trial on the effect of the above mentioned therapy we first want to know, by means of this study, if the conduct of such a large trial is feasible.

Study objective

To asses the feasibility of conducting a larger trial to evaluate the effect of a psychological intervention on well-being of patients on LHRH analogs in the treatment of prostate cancer and their partners.

Study design

Multi-centre, randomized, clinical trial (RCT).

Intervention

A psycho-oncological intervention given in groups.
Group 1 (n=25 patients + partners) will receive the psycho-oncological intervention in 8 sessions (1 intake consult (2 hours), 6 group therapy sessions (by means of information sessions) lasting 2 hours (first 3 with an interval of 1 week, the last 3 with an interval of 2 weeks) followed by one group session 1 month later.

Group 2: (n= 2l intervention group 1) and at 1 year. The primary endpoint will be the difference between change in HADS scores at baseline (T0) and after the intervention period of 16 weeks (T1)) between patients in group 1 and group 2.5 patients + partners) will receive usual care

Study burden and risks

no risks are being expected.

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

- Patient and partner must give written (personally signed and dated) informed consent

before completing any study-related procedure.
- Histologically confirmed diagnosis of prostate cancer on biopsy.
- Locally advanced or metastasised prostate cancer in need of hormonal treatment.
- On LHRH analogue treatment for a minimum of 5 months (at inclusion).
- Patients and their partner are able to fill out questionnaires, attend group sessions and give consent
- Having a female partner

Exclusion criteria

-Serious psychiatric difficulties
-Life expectancy < 12 months

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2012
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	07-02-2012
Application type:	First submission

Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	07-05-2012
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	08-05-2012
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	15-02-2013
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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
ClinicalTrials.gov	NCT01562522
CCMO	NL38379.100.11