# CLINICAL PROTOCOL for the INVESTIGATION Of the ProSpace* Balloon Spacer Pivotal Study BP-007

Published: 26-02-2020
Last updated: 10-04-2024

to demonstrate that the ProSpace, when properly inserted between the prostate and the rectum is safe and effective in reducing the volume of the rectum receiving greater or equal to 70 Gy (VRectum70) by means of IMRT in prostate cancer patients...

| | |
|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Prostatic disorders (excl infections and inflammations) |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON54912

**Source**
ToetsingOnline

**Brief title**
ProSpace* Balloon Spacer Pivotal Study BP-007

### Condition

- Prostatic disorders (excl infections and inflammations)

**Synonym**
prostate cancer, prostate carcinoma

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** BioProtect Ltd.
**Source(s) of monetary or material Support:** BioProtect Ltd.

## Intervention

**Keyword:** Device, Prostate cancer, Radiotherapy

## Outcome measures

### Primary outcome

There are two co-primary endpoints, one for safety and one for effectiveness.

The primary safety endpoint is based on the occurrence of Grade 1 or greater rectal adverse events and implantation procedure related adverse events with a duration of at least 2 days through the first six months.

The primary effectiveness endpoint is assessed only for subjects who receive the ProSpace device. The primary effectiveness endpoint is a binary assessment of whether a subject obtains at least a 25% reduction in the volume of the rectum receiving greater than or equal to 70 Gy (VRectum 70). If we denote ve to be the percentage of subjects meeting the VRectum 70 success criteria in the ProSpace Balloon arm.

### Secondary outcome

• The rate of Grade 2 or greater rectal or implantation procedure related adverse events with a duration of at least 5 days and implantation procedure related adverse events in the ProSpace Group subjects compared to Control Group subjects in the 6 month follow-up period post marking and/or balloon implantation.

• Degree of all GU acute toxicity as determined by the Expanded Prostate Cancer Index Composite (EPIC).

• Additional dosimetry parameters (DRectum100, DRectum90, DRectum80, DRectum70) will be evaluated in the balloon arm only, where subjects will serve as their

own control (dosimetry reduction after balloon implantation) as the dosimetry

parameters are compared to their baseline values per subject.

• Core lab evaluation of distance of rectal wall from the prostate at baseline

and last XRT visit. This data will be measured and quantified.

# Study description

### Background summary

The ProSpace* Balloon System consists of the balloon and it*s deployer. The ProSpace Balloon (*ProSpace*) is intended to temporarily position the anterior rectal wall away from the prostate during radiotherapy for prostate cancer and in creating this space it is the intent of the ProSpace to reduce the radiation dose delivered to the anterior rectum.
This randomized controlled trial will demonstrate that ProSpace, when used in prostate cancer patients undergoing radiotherapy by means of IMRT, reduces the radiation dose delivered to the anterior rectum.

### Study objective

to demonstrate that the ProSpace, when properly inserted between the prostate and the rectum is safe and effective in reducing the volume of the rectum receiving greater or equal to 70 Gy (VRectum70) by means of IMRT in prostate cancer patients undergoing radiotherapy

### Study design

This study will be a prospective, multi-center, randomized, double-arm, single blind, concurrently controlled study.

### Intervention

One group receives IMRT + marking + ProSpace implantation and the other group receives IMRT + marking. The ProSpace will be inserted during the same session as the marking.

### Study burden and risks

Risks associated with the use of the ProSpace Balloon System in conjunction with the control procedure (marking and IMRT) are expected to be comparable to

the risks associated with the control procedure alone. BioProtect believes that the potential benefit for the patients in the ProSpace Balloon group is higher than the potential risk. Inserting the ProSpace Balloon in situ between the prostate and the rectum will enable admission of higher dosage whether as total (accumulative) or per session (hypofractionation) or both, potentially reducing acute and late and chronic rectal toxicity.
The insertion of the ProSpace Balloon is usually harmless, however procedure related complications cannot entirely be excluded. The assumed potential risk of using the ProSpace Balloon is mainly the potential risk of rectal perforation and from injury during the implantation procedure. It should be noted however, that unlike the late complications associated with high-dose radiation that are chronic and may take years for resolution, this potential risk is temporary and reversible.

# Contacts

**Public**
BioProtect Ltd.

Tsur St. 8
Tzur Yigal 4486200
IL
**Scientific**
BioProtect Ltd.

Tsur St. 8
Tzur Yigal 4486200
IL

# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adults (18-64 years)
Elderly (65 years and older)

## Inclusion criteria

- Be at least 18 years of age;
- Have been histologically diagnosed with invasive adenocarcinoma of the prostate, at clinical stage T1-T3 that is locally confined or extracapsular with no posterior extension (i.e., not involving the rectum);
o The stage of adenocarcinoma will be determined by biopsy. For patients who have very-low or low-risk prostate cancer (i.e., T1c or T2a, Gleason less than or equal to 3+3, and PSA less than 10 ng/mL), the biopsy may be taken up to 9 months prior to screening. For all others, the biopsy must be done no greater than 6 months prior to screening.
o The presence/absence of posterior extension will be determined by MRI. For patients who have very-low or low-risk prostate cancer (T1c or T2a, Gleason less than or equal to 3+3, and PSA less than 10 ng/mL), the MRI may be taken up to 9 months prior to screening. For all others, the MRI must be taken no greater than 6 months prior to screening.
- Be scheduled for radiation therapy (XRT) for prostate cancer by means of IMRT and
- Be willing to adhere to the follow-up schedule and protocol requirements.

## Exclusion criteria

- Pelvic lymph node radiotherapy is planned;
- Any prior invasive malignancy (except non-melanomatous skin cancer) unless the subject has been disease free for a minimum of 5 years;
- Prior radical prostatectomy;
- Prior cryosurgery or radiotherapy for prostate cancer, or other local therapy for prostate cancer;
- Prior radiotherapy to the pelvis, including brachytherapy;
- American Urological Assn. (AUA) Symptom Score > 20;
- Active inflammatory bowel disease;
- Known or suspected rectal carcinoma;
- History of prior surgery involving the rectum or anus;
- Venereal warts in the region;
- Prior surgical procedure involving the peri-rectal and/or peri-prostatic area;
- Current urinary tract infection;;
- Acute or chronic prostatitis;
- Acute infection requiring intravenous antibiotics at the time of screening;
- Uncontrolled bleeding disorders;
- Unsuitability for anesthesia in the opinion of the anesthesiologist;
- Currently taking anticoagulants or NSAIDS that cannot be stopped for sufficient time prior to the implantation procedure;
- EU citizens may not be enrolled by sites located at any site that is not GDPR compliant;

- Currently incarcerated or
- Participation in any other investigational drug, biologic or medical device study within the 30 days prior to the study surgery.
- Intra-operative exclusion criteria for the balloon arm subjects only: inability to perform proper dissection between prostate and rectum.

# Study design

## Design

| | |
|---|---|
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Single blinded (masking used) |

**Primary purpose:** Prevention

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 17-07-2020 |
| Enrollment: | 40 |
| Type: | Actual |

## Medical products/devices used

| | |
|---|---|
| Generic name: | ProSpace Balloon Spacer |
| Registration: | Yes - CE intended use |

# Ethics review

Approved WMO

| | |
|---|---|
| Date: | 26-02-2020 |
| Application type: | First submission |
| Review commission: | METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht) |

Approved WMO

| | |
|---|---|
| Date: | 02-06-2020 |
| Application type: | Amendment |
| Review commission: | METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht) |

# 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 | NCT03400150 |
| CCMO | NL71222.068.19 |