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SpaceOAR post-market registry study

Submission date 09/10/2025	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 04/11/2025	**Overall study status** Ongoing	
Last Edited 04/11/2025	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims
Space OAR/SpaceOAR Vue Systems are biodegradable medical devices that are implanted between the prostate and rectum to temporarily move part of the rectal wall away from the prostate during radiation therapy for prostate cancer. Studies have shown these can lead to a reduced dose of radiation to the rectum and therefore reduce side effects from radiation. These spacers have been used in cancer treatment centres in the UK, as well as Europe and other countries, for over 6 years.
Recently, concerns have been raised by regulators that there is little data about the long-term safety of rectal hydrogel spacers for use in conjunction with radiotherapy treatment for prostate cancer. To address this, this study will collect data about the short-term side-effects and long-term safety of SpaceOAR and SpaceOAR Vue rectal hydrogel spacers in men who receive them in the UK and France. Men who have agreed to receive these spacers as part of their standard medical care will be asked to take part in the study whereby data about their treatment and health will be collected from their medical records and from members of the clinical team who deliver their treatment.

Who can participate?
Men aged 18 years and over with a confirmed diagnosis of prostate cancer, who have been recommended to undergo radiation therapy, and are planning to undergo implantation of a SpaceOAR hydrogel spacer as part of their standard medical care

What does the study involve?
During the study, participants will be asked to complete questionnaires over a maximum period of 36 months from the date they receive a spacer. The multiple-choice questionnaires will ask questions about quality of life which are related to participant's treatment for prostate cancer. The questionnaires and safety data will be collected and recorded before, during and after the implantation of the hydrogel spacer and radiotherapy treatment. Follow up appointments arranged by their hospital normally stop about 24 months after their cancer treatment. By taking part in the study, participants will be asked to continue to have these appointments for up to 36 months after their hydrogel spacer implantation.
Most of the questionnaires in this study will be completed remotely (online or via post, if needed). The first questionnaire will be when participants consent to take part in the study, and

then at 75 days, and 6, 12, 24 and 36 months after the hydrogel spacer implantation. The questionnaires will ask about your health and quality of life related to prostate cancer. Participation in the study will finish after your 36-month visit and questionnaire completion.

What are the possible benefits and risks of participating?
This study involves monitoring participants health at appointments which are 2 and 3 years their hydrogel spacer implantation. These are additional to the standard care normally received which may be seen as beneficial. Otherwise, participants will not physically benefit from participating in this study. However, medical science and future patients may benefit from their participation. We do not foresee any risks to participants who decide to take part in the study.

Where is the study run from?
Sheffield Hallam University (UK)

When is the study starting and how long is it expected to run for?
December 2024 to January 2030

Who is funding the study?
Boston Scientific Corporation (manufacturer of the SpaceOAR Systems)

Who is the main contact?
1. Dr Grace Price, grace.price@shu.ac.uk
2. Dr Saïd Ibeggazene, S.Ibeggazene@shu.ac.uk.

Contact information

Type(s)
Scientific

Contact name
Dr Said Ibeggazene

Contact details
Sheffield Hallam University
Work Address Office F507
Robert Winston Building
Broomhall Road
Sheffield
United Kingdom
S10 2BP
+44 (0)1142255562
said.ibeggazene@nhs.net

Type(s)
Scientific

Contact name
None OASIS Study Team

Contact details

Sheffield Hallam University
Work Address Office F507
Robert Winston Building
Broomhall Road
Sheffield
United Kingdom
S10 2BP
+44 (0)1142253586
sth.oasis@nhs.net

Type(s)
Scientific

Contact name
Dr Grace Price

Contact details
Sheffield Hallam University
Work Address Office F507
Robert Winston Building
Broomhall Road
Sheffield
United Kingdom
S10 2BP
+44 (0)1142255839
grace.price@shu.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
341038

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 68734

Study information

Scientific Title
OASIS: SpaceOAR post-market registry study: assessing the safety and acceptability of SpaceOAR use with prostate radiotherapy

Acronym
OASIS

Study objectives
To document the safety, acceptability and long-term outcomes of SpaceOAR and SpaceOAR Vue hydrogel rectal spacers in subjects undergoing radiation therapy (External Beam Radiotherapy or brachytherapy) to treat prostate cancer.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 03/09/2025, East of Scotland Research Ethics Service REC 1 (EoSRES, Tayside Medical Science Centre, Residency Block Level 3, George Pirie Way, Ninewells Hospital and Medical School, Dundee, DD1 9SY, UK; Tel: not provided; tay.eosres@nhs.scot), ref: 25/ES/0073

Study design
Observational; Design type: Cohort study

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Prostate cancer

Interventions
DESIGN
This observational multi-centre, multi-national study uses a prospective cohort design. This design was chosen because the study is intended to act as an enhanced form of post-marketing surveillance for the SpaceOAR rectal spacer system with the primary purpose of assessing the safety of the system in usual care. This device is currently under a NICE special arrangements recommendation and collection of further safety data is warranted.

RECRUITMENT
Participants will be identified as those in routine clinical care offered radiotherapy with curative intent for prostate cancer during the recruitment period for the study. All patients offered curative-intent radiotherapy for prostate cancer will be recorded in a screening log to track whether they were offered spacer insertion, whether they chose to proceed with the procedure, and whether they consented to share their contact details with the research team at Sheffield Hallam University (SHU).

The OASIS study will offer participants enhanced monitoring of their experiences with the SpaceOAR device as part of their usual care. When patients are approached by their clinician regarding the possibility of spacer implantation, they will be informed that additional data collection is required for all participants receiving the device. To facilitate this process, a research team at Sheffield Hallam University (SHU) are conducting a formal study at certain NHS sites across the UK. Clinicians will explain that, if the patient chooses to proceed with the spacer, their routine safety data will be included in the study with their consent. Additionally, participants will be invited to complete questionnaires, which will provide valuable data if they are agreeable to this.

The participant's direct care team will first seek verbal consent to share their contact details to the research team at SHU. The direct care team will also provide the participant with a Patient Information Sheet and securely forward the patient's referral details to the SHU research team via encrypted email.

A member of the SHU research team will then contact the prospective participant by telephone to offer further information about the study and, if necessary, provide another copy of the Patient Information Sheet. The prospective participant will have opportunity to review the study materials and discuss any aspects of the study with the SHU research team, including questionnaire and data collection processes.

If the participant decides to take part, informed consent will be obtained over the telephone. The SHU researcher will then enrol the participant into the study during the same call.

DATA COLLECTION
PROMS:
Participants enrolled into the study will be asked to complete a series of Patients-Reported Outcome Measures (PROMs):
- prior to their spacer insertion (remotely - telephone - usually during the consent call)
- on the day of their spacer insertion (in person)
- on the day of radiotherapy initiation (in person)
- 75 days post-spacer insertion (remotely - online or post)
- 6 months post-spacer insertion (remotely - online or post)
- 12 months post-spacer insertion (remotely - online or post)
- 24 months post-spacer insertion (remotely - online or post)
- 36 months post-spacer insertion (remotely - online or post)

PROMs include:
- EPIC-26: A 26-item multiple choice questionnaire assessing symptoms and quality of life impacts of prostate cancer treatment.
- Vaizey Incontinence Score: A 7-item scoring system to measure the severity of faecal incontinence
- International Prostate Symptoms Score (IPSS): A 8-item scoring tool evaluating urinary symptoms
- Symptoms Index: A 16-item scoring system to assess the impact of prostate cancer treatment.

Completion of the PROMs is expected to take approximately 10-20 min, based on feedback from a PPIE group. Those participants who choose to complete PROMS online will receive either login credentials or a secure unique web link, allowing them access the questionnaires from any internet-enabled device, such as a computer, tablet, or smartphone.

In addition to the above, participants will also be asked to complete a SpaceOAR-specific patient reported questionnaire immediately after their SpaceOAR insertion, or within 10 days of the procedure, prior to radiotherapy. Usual care for patients who have received a spacer insertion includes outpatient appointments at approximately 75 days, 6-month, 12-months post-procedure.

As part of the study, participant may be invited to attend additional follow-up appointments at 24 and/or 36 months post-spacer insertion to monitor and record any adverse events. These follow-ups may take the form of a brief telephone consultation with their direct care team, or an

outpatient appointment. These additional follow-ups are not typically part of standard care, however any clinical data collected will be used by the direct care team to inform the patient's ongoing care.

Case Report Forms:
The participant's direct care team and NHS site research staff will be responsible for completing CRFs for all consented participants to capture data on associated treatments, radiotherapy treatment plans and adverse events at each study timepoint. Additional study CRFs - such as SAE reports, study Withdrawal forms and Notification of Death -will also need to be completed by the NHS research team as required.

STUDY TIMELINE
Protocol finalisation, database development and internal review, ethical approval, site recruitment, site set-up, participant recruitment, 12-month recruitment report, follow-up data collection and monitoring, site closure, data analysis, preparation of final study report, archiving.

INTERIM REPORTING
A 12-month recruitment report is planned to be produced up to 15 months following the recruitment of participants in both the UK and France. No interim analysis is planned.

Researcher bias in not anticipated to be a concern in this study as the main data sources are routine clinical adverse event reporting and self-administered questionnaire data. Furthermore, the study research team and sponsor will be acting independently of the device manufacturer.

Intervention Type
Device

Phase
Not Applicable

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

Primary outcome(s)
1. Proportion of subjects experiencing symptoms (PROMs), adverse events (CTCAEv5.0) or abnormal imaging (MR/CT) related to the procedure of SpaceOAR/SpaceOAR Vue System hydrogel within 30 days of implantation (as adjudicated by the independent Clinical Events Committee)
2. The proportion of subjects with Grade ≥2* gastro-intestinal/ano-rectal (GI) toxicity (CTCAE v5. 0) within 3 years of receiving radiation therapy

Key secondary outcome(s))
1. Proportion of subjects with relevant Grade ≥2* gastro-intestinal/ anorectal (GI) toxicity at 12, 24 and 36 months
2. Proportion of subjects with relevant Grade ≥2* genitourinary (GU) toxicity at 12, 24 and 36 months
3. Impact of treatment on bowel function as measured on the bowel domain of EPIC26 up to 3 years post radiation therapy (PROMs)
4. Impact of treatment on urinary, sexual, and overall Quality of Life (QoL) (EPIC26) assessments up to 3 years post radiation therapy (PROMs)
5. Physician rating of SpaceOAR/SpaceOAR Vue placement on a Likert scale of 1 (very difficult)

to 5 (very easy) at time of spacer insertion
6. Patient-reported perception of procedure relative to biopsy procedure at time of spacer insertion
7. Overall mortality and causes of mortality at 3 years
8. Selection criteria for placement of SpaceOAR/SpaceOAR Vue system
9. Onset time of Grade ≥ 2* gastro-intestinal/ano-rectal toxicity
10. Onset time of Grade ≥ 2* genito-urinary toxicity using EPIC-26 and IPSS

Completion date
31/01/2030

Eligibility

Key inclusion criteria
1. All patients with a clinical diagnosis of prostate cancer planned to undergo treatment with curative intent at selected sites in the UK subject to SpaceOAR being used as usual standard of care
2. Age >=18 years old
3. Capacity to provide verbal, informed consent for participation over the telephone

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Male

Key exclusion criteria
Patients lacking the capacity to provide informed consent, including those unable to understand verbal explanation or written information in English, or who have specific communication needs

Date of first enrolment
24/11/2025

Date of final enrolment
01/03/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Chesterfield Royal Hospital NHS Foundation Trust
Chesterfield Road
Calow
Chesterfield
United Kingdom
S44 5BL

Study participating centre
Maidstone and Tunbridge Wells NHS Trust
The Maidstone Hospital
Hermitage Lane
Maidstone
United Kingdom
ME16 9QQ

Study participating centre
East and North Hertfordshire Teaching NHS Trust
Lister Hospital
Coreys Mill Lane
Stevenage
United Kingdom
SG1 4AB

Study participating centre
Royal Free London NHS Foundation Trust
Royal Free Hospital
Pond Street
London
United Kingdom
NW3 2QG

Study participating centre
Guy's and St Thomas' NHS Foundation Trust
St Thomas' Hospital
Westminster Bridge Road
London
United Kingdom
SE1 7EH

Study participating centre
The Clatterbridge Cancer Centre NHS Foundation Trust
Clatterbridge Hospital
Clatterbridge Road
Bebington
Wirral
United Kingdom
CH63 4JY

Study participating centre
Norfolk and Norwich University Hospitals NHS Foundation Trust
Colney Lane
Colney
Norwich
United Kingdom
NR4 7UY

Study participating centre
Burnley General Hospital
Casterton Avenue
Burnley
United Kingdom
BB10 2PQ

Sponsor information

Organisation
Sheffield Teaching Hospitals NHS Foundation Trust

ROR
https://ror.org/018hjpz25

Funder(s)

Funder type
Industry

Funder Name

Boston Scientific Corporation

Alternative Name(s)
Boston Scientific, Boston Scientific Corp., BSC

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

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?
Participant information sheet	version 2.0		28/10/2025	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes