SARveillance Trial

Up-Date March 2022

An international, randomised controlled trial with additional patient-preference arms of high versus lower intensity radiological surveillance following resection of primary retroperitoneal, abdominal and pelvic soft tissue sarcoma

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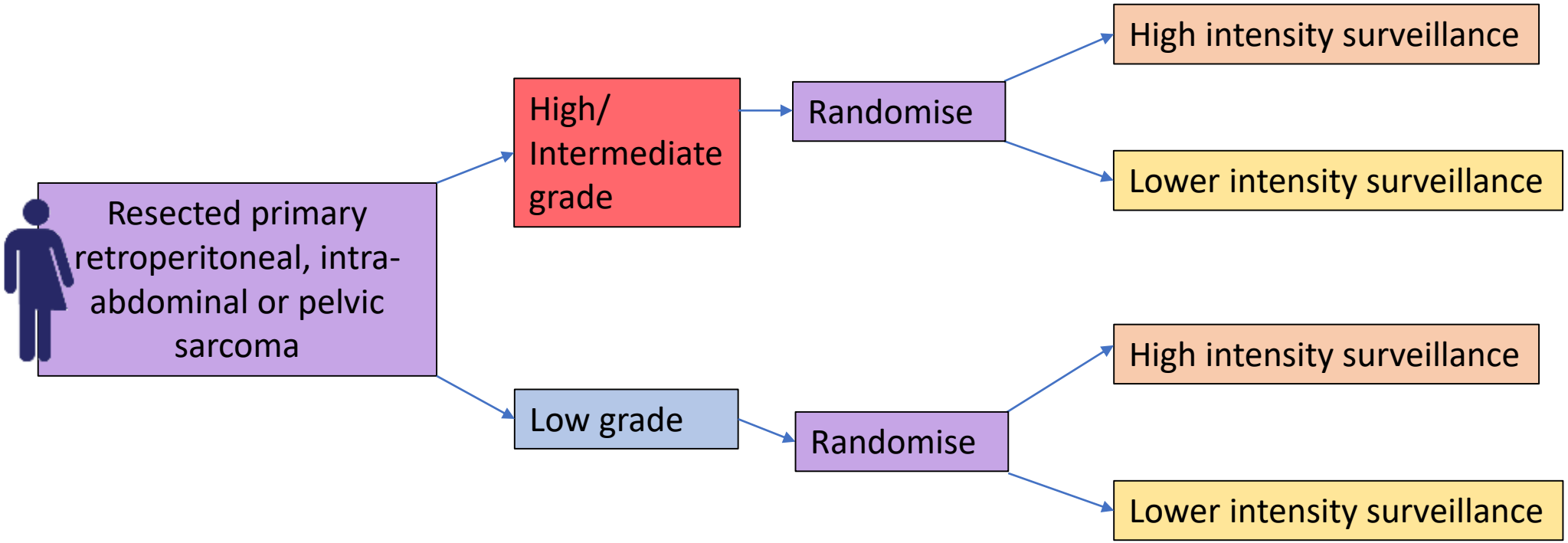
SARveillance Trial Schematic



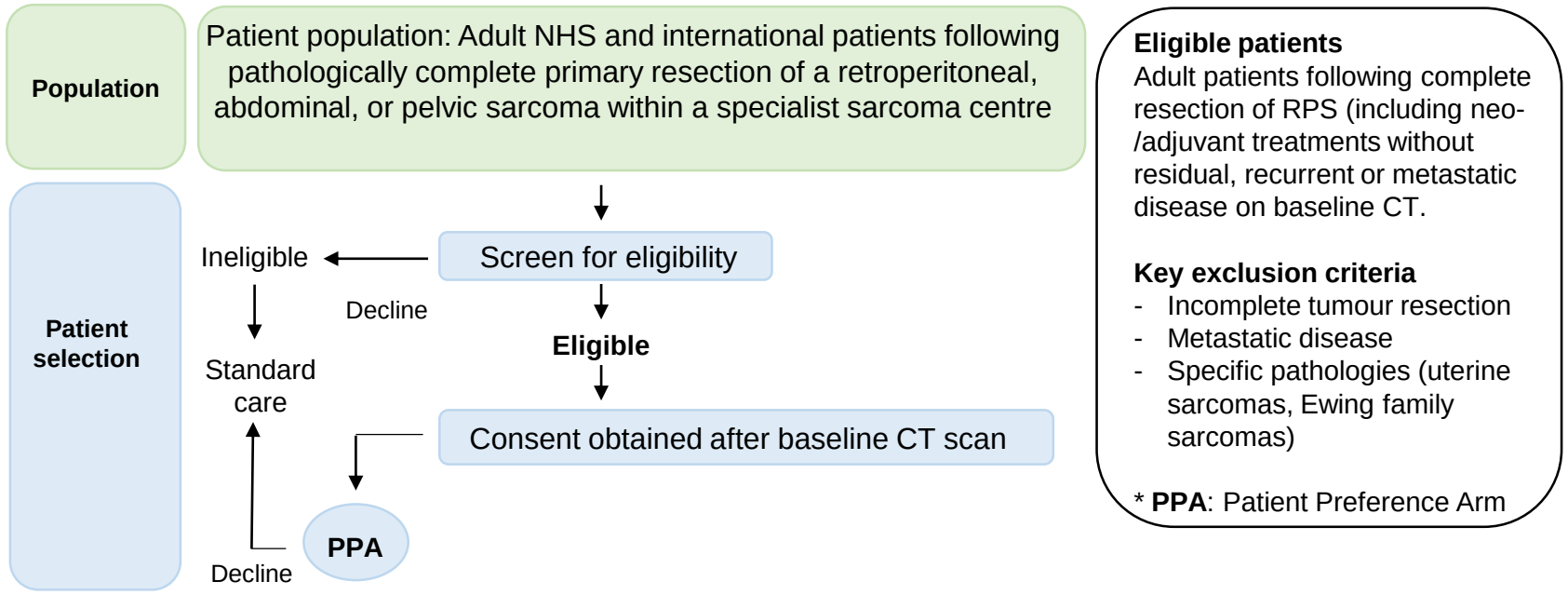
SARveillance Up-date

- NIHR HTA funding application has been submitted 4th Jan 2022

- SoECAT accepted by NIHR Clinic Research Network – assessed as no additional treatment costs (including patient preference arms)
  - Proposed start date: 01/01/2023
  - Duration: 120 months (31/12/2032)
  - Estimated research cost (excluding NHS Support & Treatment costs): **£1,752,373.00**
  - Estimated NHS support costs: **£5,951.40**
  - Estimated NHS excess treatment costs: **-£276,448.80**

- Outcome of dialogue with HTA funding administration team over international funding for trials that cannot be performed within the NHS alone
  - Centralised funding for CRCTU to coordinate running of the trial
  - Direct costs of international centres cannot be funded by a HTA grant - matched funding applications to be done in parallel - *National Cancer Institute, USA; Canadian Institute of Health Research, Canada; Cancer Council, Australia; institutional funding with prospective registry, Europe*
  - Country specific national coordinating centres

SARveillance – patient population & selection

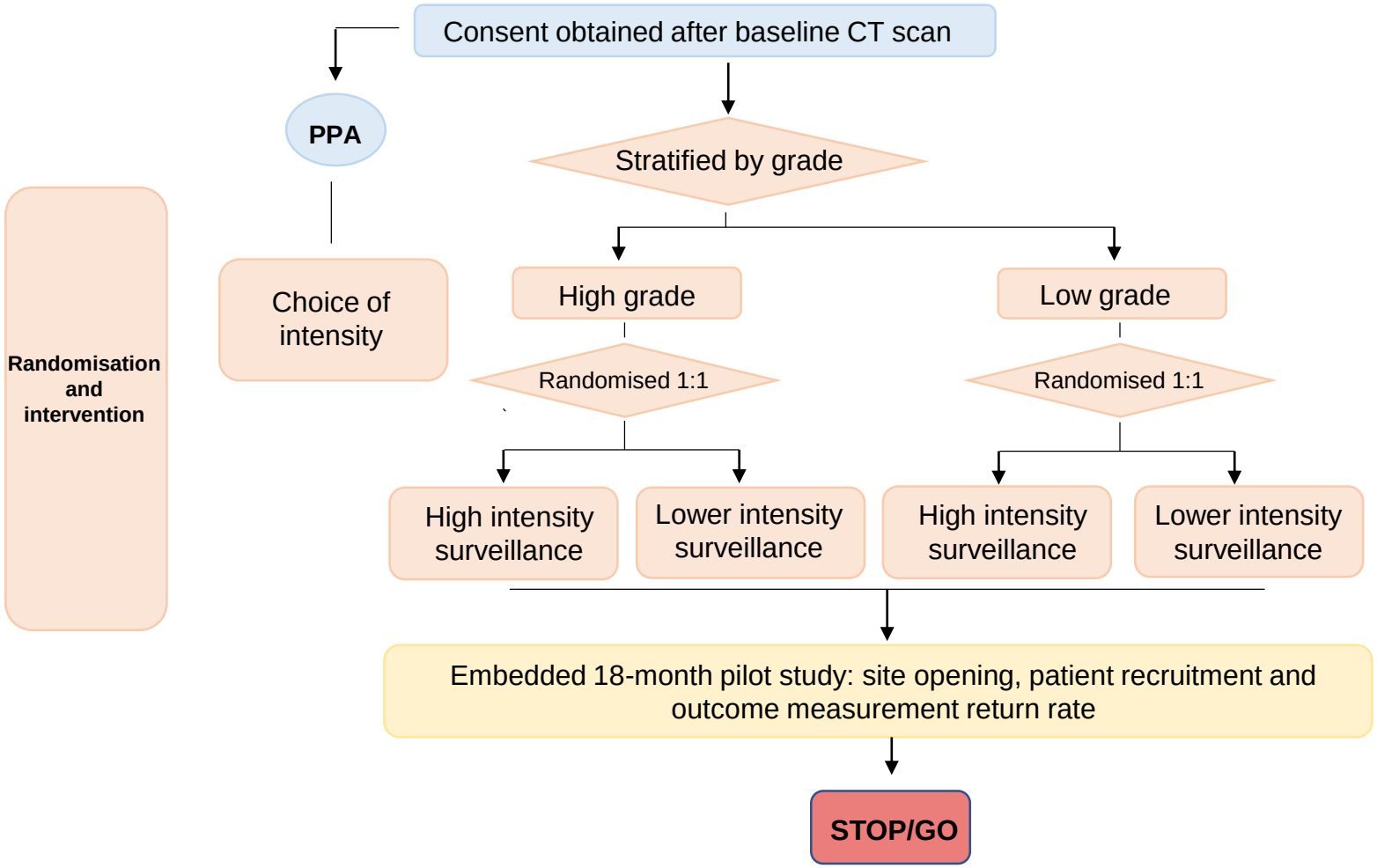


Eligible patients
Adult patients following complete resection of RPS (including neo-/adjuvant treatments without residual, recurrent or metastatic disease on baseline CT.

Key exclusion criteria
- Incomplete tumour resection
- Metastatic disease
- Specific pathologies (uterine sarcomas, Ewing family sarcomas)

* **PPA**: Patient Preference Arm

SARveillance – randomisation & intervention



SARveillance – outcomes & analysis

Outcomes

Primary

Emotional functioning domain of EORTC QLQ-C30 up to 5 years after surgery

Secondary

Overall survival
Cancer worry scale (EORTC library)
EuroQol Group EQ-5D-5L
Cost-effectiveness

Analysis

Randomised target: n=584; PPA target= additional 25% of randomised target

- Impact of surveillance intensity on mean emotional functioning scores
- Impact of surveillance intensity on overall survival
- Health-economic analysis

Data from PPA groups to be analysed separately from randomised trial arms

SARveillance Up-date

Three year PhD program to start in April 2022 – Danielle Maes

I. International multi-centre retrospective project - impact of post-operative radiological surveillance intensity on oncological outcomes and management of distant and locally recurrent disease -> proposed through TARPSWG studies committee

II. Qualitative study - semi-structured interviews (25 to 35 / thematic saturation) to assess patient's and clinicians' individual attitudes to and motivation for surveillance intensities; review of topic guide and interview questions by PPI panel

III. Calculation of cost burden associated with high versus lower intensity radiological surveillance; based on average resource use from retrospective data analysis (part I)

SARveillance Up-date

I. International multi-centre retrospective project – proposed through TARPSWG research evaluation committee

Inclusion criteria

- Adult patients (age > 18 years)
- Primary resection of retroperitoneal, abdominal, or pelvic soft-tissue sarcoma between 1 April 2011 and 1 April 2021
- R0/R1 resection
- Histological subtypes: well-differentiated liposarcoma, dedifferentiated liposarcoma, pleomorphic liposarcoma, myxoid liposarcoma, leiomyosarcoma, synovial sarcoma, pleomorphic sarcoma, spindle cell sarcoma, undifferentiated sarcoma, myxofibrosarcoma, MPNST, SFT, and high-grade sarcoma NOS.

Exclusion criteria

- Metastatic disease at time of diagnosis
- Reoperation for recurrent soft tissue sarcoma
- Re-resection following previous inadequate surgery
- R2 resection
- Histological subtypes: uterine sarcomas, prostatic stromal sarcoma, extra-skeletal Ewing's Sarcoma, GIST, rhabdomyosarcomas, PNET or other small round blue cells sarcoma, PEComa, osteosarcoma, chondrosarcoma, fibromatosis, epithelial tumours, multifocal disease.

SARveillance Up-date

I. International multi-centre retrospective project – proposed through TARPSWG research evaluation committee

Primary objective

- Impact of surveillance imaging intensity on overall survival and disease-free survival

Secondary objectives

- HE assessment of high versus lower intensity radiological surveillance
- Determination of most common mode of recurrence identification (imaging versus symptoms)
- Assessment of management of local or distant recurrence (number/nature of interventions, time to intervention from radiological diagnosis of recurrence, number of interval scans until intervention)
- Adherence to the intended surveillance protocol, comparing proposed surveillance intensity to observed intensity within the first 5 years of follow-up; proxy measure of bias (i.e., higher grade tumours received more intense surveillance than intended)
- Sarculator, aim to derive nomogram cut-off values as a guidance towards the most appropriate assignment of patients to either high or lower intensity radiological surveillance

SARveillance Up-date

I. International multi-centre retrospective project – proposed through TARPSWG research evaluation committee

Data collection

- Survey of the current imaging intervals and modalities will be undertaken to include TARPSWG specialist centres
- Submission of anonymised data - data extraction according to a pre-defined protocol using routinely collected Electronic Health Records or Paper Patient Records onto a data extraction template
- Data could be extracted from RESAR where possible overseen by the RESAR Governance Committee
- To quantify adherence to proposed surveillance intensity – as outlined in the institution's surveillance guidelines - the observed surveillance intensities will be categorised into 'compliant', or 'non-compliant' to the intended protocol, within the first 5 years of follow-up

Participation / questions / comments

- Still time to participate
- Thank you all for your support - especially the contributing centres!

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