SARveillance Trial

Up-Date Nov 2022

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

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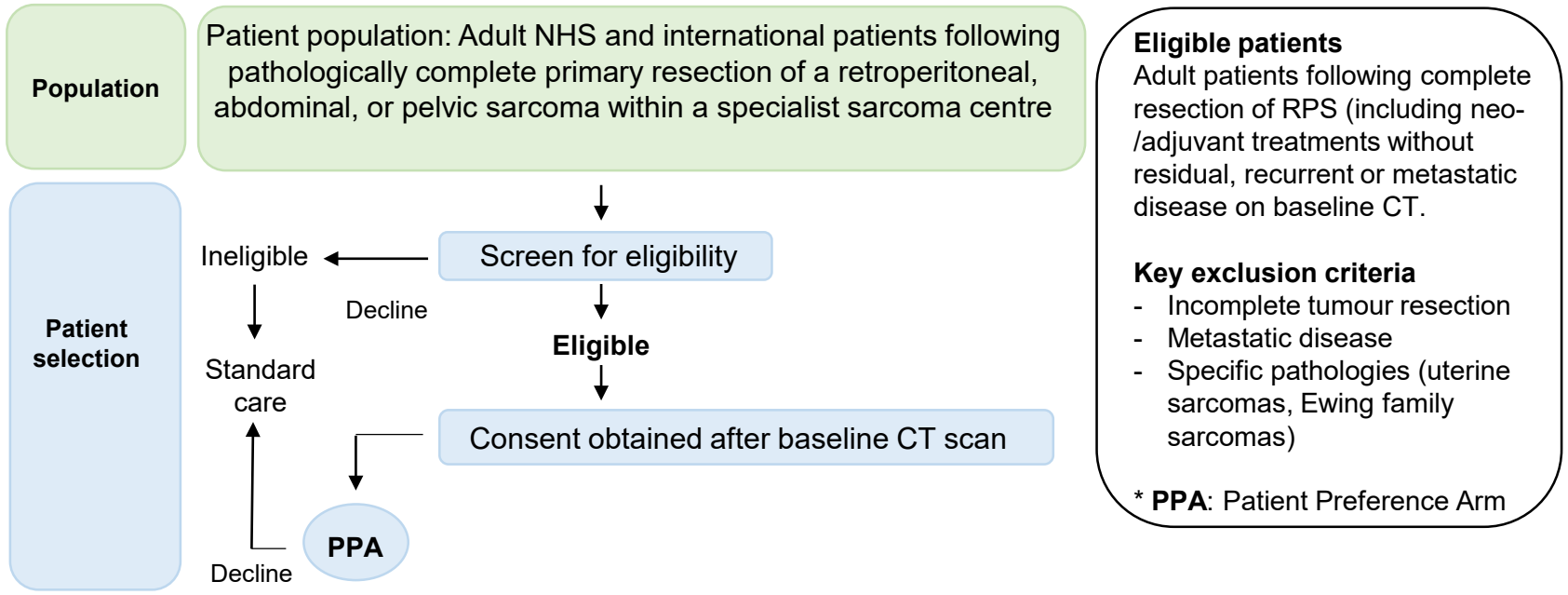
SARveillance – patient population & selection

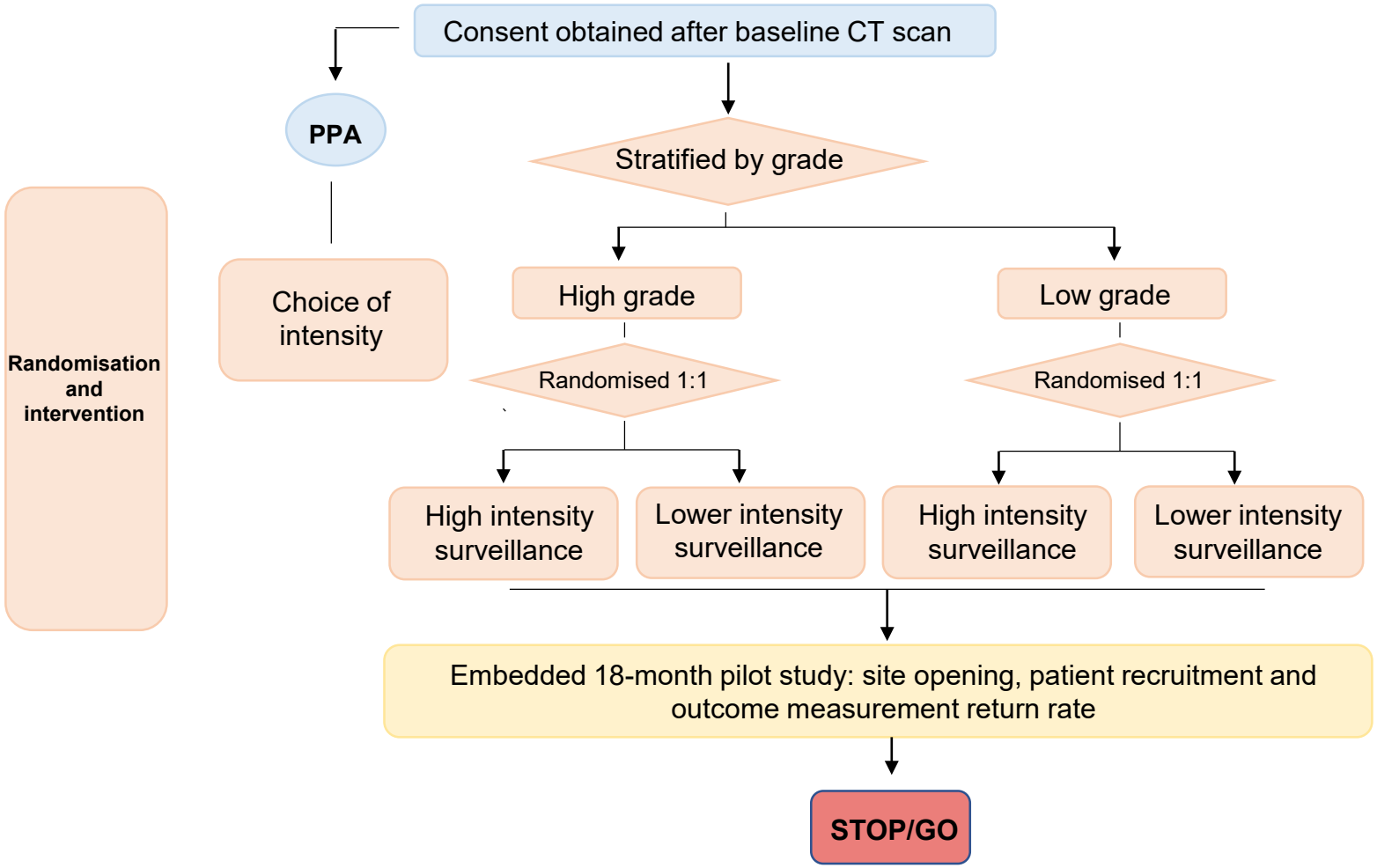


Eligible patients
Adult patients following complete resection of RPS (including neo-/adjuvant treatments without residual, recurrent or metastatic disease on baseline CT.

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

- NIHR HTA funding application was 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 - Up-date

NIHR | National Institute for Health Research

NIHR Health Technology Assessment (HTA) Programme

Application Summary Information

Programme Name: Health Technology Assessment (HTA)
Call: 21/554 Health Technology Assessment Programme Researcher-led (primary research)
Contracting Organisation: University of Birmingham

Research Title: SARveillance: 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

Research Type: Primary Research

Proposed start date to: end date (duration): From 01/01/2023 to: 31/12/2032 (120 months)
Estimated research Cost (not including NHS Support & Treatment Costs): £1,752,373.00
Estimated NHS support costs: £5,951.40
Estimated NHS excess treatment costs: -£276,448.80
Estimated Non-NHS excess treatment costs: £0.00

NIHR HTA outcome

Declined to fund

- The committee was not convinced that -
  - the findings of the study would change practice
  - the study represented value for money

SARveillance - Up-date

Re-group and consider options!

Remain committed to delivering a high quality prospective trial of surveillance

Enablers to trial delivery in the absence of major funding….

RESAR – trial within a registry (with DSA options for non-contributing centres)

Birmingham Centre for Observational and Prospective Studies (BiCOPS) have agreed to support at little cost

Small scale local funding for coordinating research nurse within BiCOPS / NIHR CRN funded research nurse support

IRB approval for Birmingham / prospective DSA for RESAR (recruit first patient in the next 12 months and then roll out)

Include collection of serum for ctDNA at time of imaging (future proofing of the study)

Continue to gather supporting evidence that patients will consent to be randomized -

Prospective questionnaire of SARveillance eligible patients - 82% would consent to be randomised and remaining 18% would agree to participation through patient preference (includes socioeconomic data) (expand coverage)

Patient and public engagement chaired by Roger Wilson

Danielle Maes – retrospective SARveillance (PhD) - interim TARPSWG guidance paper on surveillance

Questions and comments

- Thank you for your support and patience!

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