

ANZSA-led substudies for STRASS-2

NHMRC/Medical Research Future Fund, Australian Govt

Structure



Brisbane

Princess Alexandra Hospital

Local PI – Andrew Barbour

Status - open

Sydney

Royal Prince Alfred Hospital

Local PI – Peter Grimison

Status - open

Melbourne

Peter MacCallum Cancer Centre

Local PI – Anne Hamilton/ David Gyorki

Status – open, 1 patient recruited

Substudies

- Grant application included funding for a patient preferences substudy



Annals of Oncology 29: 370–376, 2018
doi:10.1093/annonc/mdx715
Published online 21 November 2017

ORIGINAL ARTICLE

Patients' preferences for adjuvant sorafenib after resection of renal cell carcinoma in the SORCE trial: what makes it worthwhile?

P. L. Blinman^{1,2*}, I. D. Davis^{2,3,4}, A. Martin^{2,3,5}, S. Troon^{2,6}, S. Sengupta^{2,7}, E. Hovey^{2,8}, X. Coskinas^{2,5}, R. Kaplan⁹, A. Ritchie¹⁰, A. Meade⁹, T. Eisen¹¹ & M. R. Stockler^{1,2,5}

Patient preferences substudy

Aim:

- to understand how patients consider the relative benefits and harms of (neoadjuvant) chemotherapy.

Methods

- Preferences are a value judgement (ie no right answer) that varies amongst individuals depending on their attitudes, experiences & priorities.
- will use the 'time trade-off method' to quantify the minimum survival benefits judged sufficient to make the harms & inconveniences of chemotherapy worthwhile.
 - Eg. Patients asked “given baseline prognosis of 5 years... how much extra time do you need to make 3 months of neoadjuvant chemotherapy worthwhile an extra... eg 1 day, 1 month, 3 months, 6 months and so on.

Patient preferences substudy

Methods (cont)

- Study would ask questions related to survival time as well as to survival rate
- Single time point questionnaire to be conducted together with QoL questionnaire

Final protocol complete. Has been shared with international sites to gauge interest.

- *Invitation to any country where english is first language to participate*
- *Planning to change the protocol (new PLCF) to allow patients who meet enrolment criteria but are unwilling/ineligible to participate in the study*

Australian led substudies – #2 PET substudy

Hypothesis:

That early on-treatment PET (post-cycle 1) will identify patients for whom further systemic therapy is futile.

Methods

Patients undergo baseline PET and repeat PET prior to cycle 2 of chemotherapy.

Will include all patients in Australia and also patients from Netherlands and selected other sites

Initial EORTC EOI showed strong interest

Study leads

Michael Hofman/Kate Moodie/David Gyorki (PMCC); Wim Oyen/Winan van Houdt (NKI)