STRASS 2 substudies

Dr David Gyorki
Peter MacCallum Cancer Centre
Melbourne, Australia

Overview

STRASS 2 in Australia

- Sponsor – Australia and New Zealand Sarcoma Association

- Funding – NH&MRC - Rare Cancer and Rare Disease of Unmet Need grant
    - incorporated into the funding proposal were two substudies

- Substudies
    - PET substudy
    - patient preference substudy

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 other sites with ready access to PET

Study coordinator

Dr Kate Moodie/David Gyorki (PMCC)

PET substudy

Details

Participating centres will upload imaging through EORTC for central review at coordinating centre (PMCC, Melbourne)

Primary endpoint is response by PERCIST measurement comparing SUV at baseline and early on-treatment scan

Centres participating in the PET sub-study require EARL, SNMMI CTN or ARTnet (Australasian Radiopharmaceutical Trials network) accreditation.

Patient preference substudy

Aim:

To understand how patients consider the relative benefits and harms of (neoadjuvant) chemotherapy

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. Kaplan[9], A. Ritchie[10], A. Meade[9], T. Eisen[11] & M. R. Stockler[1,2,5]

Patient preference substudy

Study design

Observational cohort study nested within an international, randomised clinical trial

Target population

All patients recruited to STRASS 2 in participating centres (Australia +/- international sites) will need to be able to read, comprehend and write at a sufficient level to complete study materials. Currently limited to English speaking countries

Patient preference substudy

Methods

- Preferences are a value judgement (ie no right answer) that varies amongst individuals depending on their attitudes, experiences & priorities.
- Single time point questionnaire to be conducted together with QoL questionnaire
- PPS 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.

  Study would ask questions related to survival time as well as to survival rate

Patient preference substudy

Answer these questions based on your knowledge of what having neoadjuvant chemotherapy is like. In other words, consider what you have experienced, read, or been told about its side effects and inconvenience.

WITHOUT chemotherapy your life expectancy is				**WITH** chemotherapy your life expectancy is
3 years	☐	**OR**	☐	3 years
3 years	☐	**OR**	☐	3 years and 1 month
3 years	☐	**OR**	☐	3 years and 3 months
3 years	☐	**OR**	☐	3 years and 6 months
3 years	☐	**OR**	☐	3 years and 9 months
3 years	☐	**OR**	☐	4 years
3 years	☐	**OR**	☐	4 ½ years
3 years	☐	**OR**	☐	5 years

Patient preference substudy

FORMS	Completed by	Baseline (after consent but before randomisation)	Follow-up (24 weeks or 36 weeks post randomisation)
Consent form (as per STRASS 2)	Patient	X	
Registration form (as per STRASS 2)	Study nurse	X	
Patient Questionnaire Baseline	Patient	X	
Patient Questionnaire Follow-up	Patient		X

Clinician preference study to follow

Watch this space…

Questions

david.gyorki@petermac.org