



Central South Coast
Cancer Research Network

Development of a EORTC Questionnaire for Patients with Neuro Endocrine Tumours

Phase 3 Study

Plans for Phase 4

NET / Carcinoid Tumours

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Phase 3 Summary

- 180 patients recruited into phase 3.
- Phase 3 report to be sent in and then reviewed.
- Final questionnaire is G.I.NET 21.
- G.I.NET 21 translations planned in Dutch, French, German, Italian and Swedish.



Scales for G.I.NET 21

Symptom Scales

- Endocrine (3)
- G.I. (5)
- Muscle/ bone pain (1)

Functional scales

- Treatment (2)
- Anxiety (7)
- Sexuality (1)
- Social (1)
- Communication(1)
communication is scored positively so analysed as symptom scales.



Phase 4 Study for Validation of NET Module

- We would like this study to be done as part of a 3 armed randomised controlled study in UK, NL and in other countries to be determined:
 - in patients with GEP tumours, and
 - with positive somatostatin receptor confirmed by octreoscan.
- We plan to analyse qol data separately under EORTC rules.
- The study will compare:
 - Arm 1 Yttrium90-octreotide 4 doses
 - Arm 2 Lutetium177-octreotate 4 doses
 - Arm 3 Y-octreotide 2 doses then Lu-octreotate 2 doses
- Treatment dispensed from Rotterdam.
- Awaiting confirmation how study is to be funded.



Aims of Study

- Effect of treatment on quality of life
- Efficacy of treatment measured by tumour response rate and tumour growth rate
- Time to progression and survival
- Safety-adverse events and laboratory evaluations



Visit Schedules and Quality of Life Assessments

- 4 Treatment blocks 6-9 weeks apart.
- Follow-up at 6 weeks, 3 months, 6 months, then every 6 months to 5 years.
- Quality of life measured using C30 and NET 21 at pre treatment and at follow ups.