



Central South Coast
Cancer Research Network

Validation of a disease-specific questionnaire module in assessing the quality of life of patients with G.I.- related NET.

Phase 4 Study

NET / Carcinoid Tumours

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Phase 4 validation study

Aims of Study

- Development of NET specific module
- Test scale structure, reliability and validity of G.I.-NET module(G.I.NET21)
- Assess quality of life using C30 and G.I.NET21 before and after various treatments



Study Background

- QoL as end point in some trials
- No disease specific QoL questionnaire for NET
- Need standardised tool with reliability and validity to detect small changes in QoL
- Use EORTC module approach to develop disease specific module to supplement EORTC QLQ-C30



Modular Development of G.I.NET21

- Phase 1: generation of relevant QoL issues from literature and interviews
- Phase 2: operationalisation of issues into 35 questionnaire items



Phase 3 summary

Phase 3 summary

- Pre-testing in 180 patients
- 21 questionnaire items
- ? Change to time scale .

Patients preference for 1 or 4 week time scales
in phase 4



Scales for G.I.NET 21

use negative scoring for all questions so severe symptoms means high score.

Symptom Scales

- Endocrine (3)
- G.I. (5)
- Treatment (3)

Symptom Single Items

- Muscle/bone pain (1)
- Body image(1)

Psychosocial Scales

Social (3)

Disease-related
worries(3)

Other Single Items

- Sexuality (1)
- Communication(1)



Inclusion Criteria

- Histological diagnosis of NET or radiological findings with raised hormones in plasma or urine
- Eligible diagnoses with/out hormones
 1. Gut primary with liver mets
 2. Lung primary with liver/abdominal mets
 3. Pancreas primary with/out mets



Inclusion criteria

- No concurrent malignancies except basal cell carcinoma of skin
- Expected survival more than 3 months
- All patients will be starting a treatment for Gastrointestinal NET, and will be put into groups 1, 2 or 3 depending on the treatment they receive.



Treatment Groups

**Group 1: Somatostatin analogues or interferon-
long term continuous treatment.**

QoL before and during long term continuous
treatment

- Patients be SMS or interferon naive
- Dose escalation is allowed
- Other treatments avoided, if possible.



Treatment Groups

Group 2: Radionucleotide therapy or systemic chemotherapy-2-6 treatments.

QoL before and during repeated treatments

- Assessments not done week of and week after treatment.
- Further group 2 treatments can be given
- Avoid group 3 treatments



Treatment groups

Group 3: Embolisation (hepatic artery or chemotherapy) or liver surgery - single treatment.

QoL before and after a single treatment

- Avoid further group 2 or 3 treatments



Treatment Groups

For Groups 2 and 3

Not had group 2 or 3 treatment within past 6 months

Patients can be on a stable dose of group 1 treatment but dose must not change by more than 50% for the duration of the study.



Assessment schedule

1 st assessment	2 nd assessment	3 rd assessment	Test re-test assessment
Within 3 weeks before treatment	3 months (+/- 3 weeks)	6 months (+/- 3 weeks)	2 weeks after assessment 3 for stable patients

No trial treatment 14 days before or during assessment for group 2(chemotherapy, radio nucleotide therapy)



Study Documentation

Assessment 1:

- QLQ-C30 and G.I.NET21
- Debriefing questionnaire
- Karnofsky performance status
- Eligibility form
- Clinical data and socio-demographic form



Study documentation

Assessment 2 and 3:

- QLQ-C30 and G.I.NET21
- Karnofsky performance status
- Follow-up form

Test-retest assessment:

- For stable patients repeat assessment done 2 weeks after assessment 3



List of investigators

- Dr Ramage-Basingstoke and London, UK.
- Louise Jones-Liverpool, UK.
- Colin Johnson-Southampton, UK.
- Cathy Bouvier-London.
- Dr Joy Ardill, Northern Ireland



More Investigators

- Dr Sezer and Dr Fleissner-Germany
- Dr Koller-Germany
- Dr Falconi and Dr Bettini- Italy
- Prof Olimpia Pino-Italy
- Dr Taal and Dr Zuetenhorst-The Netherlands
- Dr Gunnel Larsson-Sweden
- Dr Krzysztof Jeziorski- Poland



Possible new investigators

- Professor Kvols -USA
- Ramon Salazar-Spain
- Lone Astrup, Henning Gronbaek-Denmark
- Gregory Kaltsas-Greece
- David Goss-Hebrew translation



Translations

Translations Co-ordinator-Karen West

- Completed in
Swedish, German, Dutch, Greek, Hungarian,
French, Italian, Polish, Spanish, Czech,
Danish, Portuguese
- Requested in
Hebrew



Ethics submissions

- MREC process in UK
- Requirements at International centres
- Length of time

In Study Costs

Photocopying patient packs

Postage/Fax